UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 18-op-45090 *The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 17-op-45004	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

EXPERT REPORT OF SEAN NICHOLSON, PH.D.

May 10, 2019

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1. QUALIFICATIONS

1. I am a Professor in the Department of Policy Analysis and Management and the Director of the Sloan Program in Health Administration at Cornell University. I am also a Research Associate at the National Bureau of Economic Research. Prior to joining Cornell, I served as an Assistant Professor in Health Care Systems at the Wharton School of the University of Pennsylvania. I have a Ph.D. in economics from the University of Wisconsin-Madison and an A.B. in economics from Dartmouth College. My research and teaching specialty is the economics of health care. My curriculum vitae, including a list of publications, is attached as Appendix A.

2. In my academic career, I have researched the economics of the health care industry, with an emphasis on the biotechnology and pharmaceutical sectors. In this field of study, I have published articles in leading academic journals and presented my research at academic conferences. In addition, I have served as a principal investigator on research projects sponsored by the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Robert Wood Johnson Foundation, and by leading pharmaceutical companies.

3. My research projects have included identifying what types of firms are most effective at developing drugs, assessing risk in the health care industry, and determining the value of new medical technologies. I have done extensive research on the risks and uncertainties facing pharmaceutical companies. I have also conducted research and offered expert testimony in multiple cases in the pharmaceutical industry. Appendix B contains a list of cases in which I have provided deposition or trial testimony in the last four years.

4. I am being compensated at my standard billing rate of $850 per hour. I have been assisted in this matter by staff of Cornerstone Research, who worked under my direction. I receive compensation from Cornerstone Research based on its collected staff billings for its support of me in this matter. Neither my compensation in this matter nor my compensation from Cornerstone Research is in any way contingent or based on the content of my opinion or the outcome of this or any other matter.

2. ASSIGNMENT

5. I have been retained by counsel for Cephalon, Inc. ("Cephalon"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), Actavis Pharma, Inc. ("Actavis Pharma"), Actavis LLC ("Actavis LLC"), Watson Laboratories, Inc. ("Watson"), Anda, Inc. ("Anda"), and other affiliates[1] to review and respond to the opinions offered in certain expert reports submitted on behalf of Cuyahoga County and Summit County (collectively, "Bellwether Counties").[2] In particular, I have been asked to:

a. Assess whether these experts have causally linked the alleged damages suffered by Bellwether Counties to the Teva and Actavis Generic Defendants' alleged conduct.[3]

b. Evaluate the reliability of the methodologies employed in

   i. estimating damages allegedly suffered by the Bellwether Counties;

   ii. estimating the cost of abating the opioid abuse crisis; and

   iii. Identifying "suspicious" transactions from Distributors to Dispensers over the 1997–2018 time period.

6. As part of my assignment, I have reviewed academic literature, industry research, case depositions, disclosures and other relevant publicly available documents, as well as other documents produced in this litigation. A complete list of the materials I have considered in forming my opinion is attached as Appendix C. My analysis on this matter is ongoing and I

[1] Teva USA and Cephalon are referred to as the "Teva Defendants." Actavis Pharma, Actavis LLC, Watson, Warner Chilcott Company, LLC, Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City, and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida are referred to as the "Actavis Generic Defendants." In addition, I understand that Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") has been named as a defendant in this case based upon the conduct of the Teva and Actavis Generic Defendants, but contests personal jurisdiction. The opinions stated herein as to the Teva and Actavis Generic Defendants also apply to Teva Ltd.

[2] Expert Report of Professor David Cutler, March 25, 2019 ("Cutler Report"); Expert Report of Professor Thomas McGuire Damages to Bellwethers, March 25, 2019 ("McGuire Damages Report"); Expert Report of Professor Thomas McGuire Regarding Public Nuisance, March 25, 2019 ("McGuire Public Nuisance Report"); Expert Report of Craig J. Dr. McCann, March 25 2019 ("McCann Initial Report"); First Supplemental Expert Report of Craig J. McCann, April 3, 2019; Second Supplemental Expert Report of Craig J. McCann, April 15, 2019 ("McCann Supplemental Report"); G. Caleb Alexander, MD, MS, Expert Report, March 24 2019 ("Alexander Report"); and Expert report of Dr. Jeffrey B. Liebman, March 25 2019 ("Liebman Report").

[3] Plaintiffs' experts describe the alleged conduct as "the manufacturers' deceptive marketing strategy and tactics" and "failure to control the supply chain" by "fail[ing] to maintain effective controls against diversion, including monitoring and identifying excessive shipments that are potentially suspicious and to prevent such shipments." Expert Report of Professor Meredith Rosenthal, March 25, 2019 ("Rosenthal Report") ¶ 7; McGuire Damages Report, at ¶ 19.

reserve the right to supplement or amend my opinions if I receive additional information that warrants such a supplement or amendment.[4]

[4] Plaintiffs do not allege that Anda, a Distributor Defendant, engaged in any marketing conduct at issue in this case. Therefore, I have not be asked to, and did not in fact, review any information regarding Anda's conduct. Moreover, none of the Plaintiffs' experts I have been tasked with responding specifically address Anda in their reports or opinions. To the extent Plaintiffs purport to offer any of these opinions generally to all Defendants, which would include Anda, they are flawed for substantially the same reasons expressed herein.

3. ALLEGATIONS

7. Summit County and Cuyahoga County ("Plaintiffs") allege that "Marketing Defendants designed and implemented a sophisticated and deceptive marketing strategy" that misrepresented the risks and benefits of opioids.[5]

8. Plaintiffs allege that these misrepresentations were disseminated through various channels, including: "through advertising, sales representatives, purportedly independent organizations these defendants funded and controlled, 'Front Groups,' so-called industry 'Key Opinion Leaders,' and Continuing Medical Education ('CME') programs."[6]

9. According to Plaintiffs, "Defendants' conduct in promoting opioid use has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction, overdose, and death from illicit drugs such as heroin. The costs are borne by Plaintiffs and other governmental entities. These necessary and costly responses to the opioid abuse crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarcerations, treating opioid-addicted newborns in neonatal intensive care units, and burying the dead, among others."[7]

10. Plaintiffs also allege that "[t]he Marketing Defendants created a vastly and dangerously larger market for opioids. All of the Defendants [including Marketing Defendants] compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls,

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[5] Summit County Third Amended Complaint, *In Re: National Prescription Opiate Litigation*, March 21, 2019 ("Complaint"), ¶ 169. The Complaint refers to both Marketing Defendants and Distributor Defendants, collectively referred to in this report as Defendants. *Marketing Defendants* include: Purdue Pharma, L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., f/k/a Par Pharmaceutical Holdings, Inc., Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-Mcneil-Janssen Pharmaceuticals, Inc., n/k/a Janssen Pharmaceuticals, Inc., Johnson & Johnson, Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc, Cephalon, Inc., Allergan PLC f/k/a Actavis PLC, Allergan Finance, LLC, f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc, Insys Therapeutics, Inc., Mallinckrodt, PLC, Mallinckrodt LLC, SpecGx LLC, Allergan Sales, LLC, Allergan USA, Inc., Warner Chilcott Company, LLC, Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City, and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida. *Distributor Defendants* include: Cardinal Health Inc., McKesson Corporation, AmerisourceBergen Corporation, Health Mart Systems, Inc., H.D. Smith Wholesale Drug Co., Anda, Inc., Discount Drug Mart, Inc., Prescription Supply, Inc., CVS Health Corporation, HBC Service Company, RiteAid Corp., Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Walgreens Boots Alliance, Inc. a/k/a Walgreen Co., Walmart Inc., f/k/a Walmart Stores, Inc.

[6] Complaint, ¶ 171.

[7] Complaint, ¶ 20.

and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties."[8]

[8] Complaint, ¶ 493.

4. SUMMARY OF OPINIONS

11. Opioid prescriptions have been subject to federal and state laws, treatment guidelines, and regulations. In particular:

a. Prescriptions of Actiq, Fentora and other generic opioid medicines manufactured by the Marketing Defendants are subject to stringent FDA regulations.

b. The Drug Enforcement Agency ("DEA") restricts distribution of the Marketing Defendants' opioid medicines.

c. The Marketing Defendants' opioid medicines are subject to prescription drug monitoring programs ("PDMPs").

d. Other Ohio State programs monitor the Marketing Defendants' opioid product prescribing.

12. The risks associated with prescription opioids were generally well known, and if regulators, the State of Ohio and payors had acted earlier, the alleged harm to the Bellwether Counties could have been limited.

13. Based on my analysis, I find Plaintiffs' claim that the Marketing Defendants' alleged conduct "has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin" to be inconsistent with Teva Defendants' market share for branded opioids in the Bellwether Counties, as well as the marketing expenditure of the Teva USA and Generic Defendants on generic products—both of which were miniscule.

14. Dr. Cutler seeks to estimate "the share of various harms imposed on selected departments in each Bellwether government ('Bellwether divisions') that is attributable to defendants' misconduct." Specifically, Dr. Cutler considers three "categories" of harm:

a. Crime/Public Safety: Sheriff; Juvenile and County courts; Prosecutor and Public Defenders' Office; and Corrections;

b. Children/Family Related: Children and Family Services; and Children Services Board; and

c. Public Health: Alcohol/Drug/Mental Health Boards; and Medical Examiners' Office.

15. Dr. Cutler's analyses suffer from both methodological flaws and ad-hoc/unsubstantiated assumptions. In particular:

a. Dr. Cutler incorrectly assumes that absent Marketing Defendants' alleged conduct, the Bellwether Counties would have incurred none of the harms that he attributes to opioids. In doing so, Dr. Cutler ignores factors like pre-existing patient conditions and intentional deaths, due to which the Bellwether Counties would have incurred some of the same harms even absent the Marketing Defendants' alleged conduct.

b. Dr. Cutler's estimates of the "share of harms attributable to opioids," particularly with regards to Crime/Public Safety and Summit County's Coroner's Activity are unreliable. This is because he does not account for the fact that both crime and deaths can have multiple causes, so that some of them would have occurred even absent the alleged conduct of the Marketing Defendants.

c. Dr. Cutler assumes without basis that the relationship between prescription opioid shipments and mortality will be weaker than the relationship between opioid consumption and mortality.

d. Dr. Cutler's estimates of the purported "share of harms attributable to opioid shipments" of the Marketing Defendants are unreliable. Specifically, Dr. Cutler relies on Dr. Rosenthal's estimates of the share of opioid shipments due to the Marketing Defendants' alleged conduct, which I understand are deeply flawed according to Dr. Ketcham's and Dr. Chintagunta's assessment. Furthermore, Dr. Cutler's estimation methodology for assessing the impact of the shipments due to the Marketing Defendants' alleged conduct is flawed and relies on ad-hoc/unsubstantiated assumptions.

16. Dr. McGuire has submitted two reports. In the McGuire Damages Report, he estimates between $194.4 million and $223.4 million in purported damages due to costs incurred by Bellwether government departments between 2006 and 2018. In the McGuire Public Nuisance Report, he estimates a "net economic burden" of $20.1 billion between 2006–2016 due to "public nuisance," categorized into five harm groups and government costs. The government costs in the McGuire Public Nuisance Report reflect the $194.4 million to $223.4 million in purported damages estimated in the McGuire Damages Report.

17. Dr. McGuire's methodologies include several overarching errors. In particular:

a. Dr. McGuire's damages calculations rely on Dr. Cutler's share of harm estimates. Therefore, any errors in Dr. Cutler's calculations make Dr. McGuire's analyses unreliable. I illustrate the unreliability of Dr. McGuire's damages by repeating his analyses using sensitivities I calculate for Dr. Cutler's share of harm estimates.

b. In the McGuire Public Nuisance Report, he uses Dr. Cutler's share of harm estimates based on all opioid shipments, which inflate damages compared to the share of harm estimates Dr. McGuire uses in his Damages Report that are purportedly attributable to the Marketing Defendants' alleged conduct.

18. Dr. McGuire's damages calculations for the individual harm groups and government costs suffer from a number of methodological and conceptual errors. Although I am able to quantify the impact of only a subset of these errors, I show that Dr. McGuire profoundly overestimates his alleged harm calculations—by more than 80%—in the McGuire Public Nuisance Report. In addition, Dr. McGuire does not apportion these flawed and overstated damages estimates to each Defendant, rendering his findings unhelpful and irrelevant for the purposes of this litigation.

19. Dr. McCann has submitted three reports, all of which suffer from conceptual and methodological errors. Specifically:

a. Dr. McCann uses threshold filters to flag suspicious transactions of opioids shipments that he has attributed to Marketing Defendants. Dr. McCann's proposed threshold filters are ad-hoc and uninformative and he provides no justification for his choice of threshold filter levels. The filters fail to account for any of the underlying variance in dosage units, and also ignore long-run trends that may have contributed to increased opioid prescriptions that are unrelated to suspicious orders.

b. Dr. McCann also inflates the number of flagged transactions by assuming that once a transaction is flagged, all subsequent transactions should be flagged. Dr. McCann's various methodologies are not even consistent with one another, and result in substantially different estimates in the number of transactions that should have been flagged.

c. Dr. McCann's assumption that Marketing Defendants could use chargeback data to identify suspect transactions is flawed. His own analysis relies on detailed, transaction-level, ARCOS data. However, Marketing Defendants did not have access to ARCOS data. Furthermore, even with chargeback data, the supply chain of pharmaceutical products shows that Marketing Defendants

have little visibility over where the opioids they supply to distributors will eventually end up and are unable to monitor suspicious transactions using chargeback data.

20. Plaintiffs' experts, Dr. Liebman and Dr. Alexander ("Plaintiffs' Abatement Experts"), submitted expert reports purporting to estimate the cost of abating the opioid abuse crisis. Plaintiffs' abatement analyses are not causally linked to Defendants' alleged conduct. In particular,

a. Plaintiffs' Abatement Experts do not isolate the abatement costs required because of the Defendants' alleged conduct.

b. Plaintiffs' Abatement Experts do not apportion their estimates of the abatement costs to each Defendant.

5. BACKGROUND

21. Opioids are a class of drugs that include naturally occurring, semi-synthetic, and synthetic opioid drugs.[9] Natural and semi-synthetic opioids, often referred to as opiates, are derived from the juice of the opium poppy plant.[10] Medically, opioids are typically prescribed to treat moderate-to-severe pain.[11] Separate from the method of drug synthesis, prescription opioids are often classified by their rate of action and duration. Extended-release (or long-acting) opioids, such as OxyContin, are relatively slow to take effect, but have long duration of action. Conversely, immediate-release (or short-acting) opioids, such as Actiq and Fentora, take effect rapidly, but have a relatively short duration of action.[12] In addition to prescription opioids, there exist illicit opioids, most notably heroin.[13] Recently, illicit fentanyl, often mixed with heroin or other illicit drugs, has made up an increasing large portion of opioid-related overdose deaths.[14]

5.1. Opioid products of the Teva and Actavis Generic Defendants

22. The Teva and Actavis Generic Defendants are subsidiaries of Teva Pharmaceutical Industries Ltd.[15] Generics account for a significant share of their revenues.[16] Although Teva does not report revenues for individual opioid products, it lists the "most significant generic

[9] Enno Freye and Joseph Victor Levy, *Opioids in Medicine: A Comprehensive Review on the Mode of Action and the Use of Analgesics in Different Pain States* (Dordrecht, The Netherlands: Springer, 2008), p. 85. Naturally occurring opioids include morphine and codeine. Semi-synthetic opioids include oxycodone, hydrocodone, hydromorphone, and oxymorphone. Synthetic opioids include methadone, tramadol, and fentanyl. See CDC, "Opioid Data Analysis and Resources," December 19, 2018, available at https://www.cdc.gov/drugoverdose/data/analysis.html, accessed on February 22, 2019.

[10] Enno Freye and Joseph Victor Levy, *Opioids in Medicine: A Comprehensive Review on the Mode of Action and the Use of Analgesics in Different Pain States* (Dordrecht, The Netherlands: Springer, 2008), p. 85.

[11] CDC, "Commonly Used Terms," August 29, 2017, available at https://www.cdc.gov/drugoverdose/opioids/terms.html, accessed on May 9, 2019.

[12] CDC, "Opioid Overdose," August 28, 2017, available at https://www.cdc.gov/drugoverdose/opioids/terms.html, accessed on February 22, 2019.

[13] CDC, "Opioid Data Analysis and Resources," December 19, 2018, available at https://www.cdc.gov/drugoverdose/data/analysis.html, accessed on February 22, 2019.

[14] CDC, "Fentanyl," December 19, 2018, available at https://www.cdc.gov/drugoverdose/opioids/fentanyl.html, accessed on May 4, 2019.

[15] Teva, "Who We Are," available at https://www.tevagenerics.com/about-teva-generics/who-we-are/, accessed on February 14, 2019.

[16] In 2010, generics accounted for approximately 68 percent of Teva's revenues. More recently, specialty medicine has become an important component of Teva's revenue base. See Teva Pharmaceutical Industries Limited, SEC Form 20-F for the fiscal year ended December 31, 2010, filed on February 15, 2011 ("Teva 2010 20-F"), pp. 54, 59. In 2017, Teva generated $12.3 billion in revenue from all generic products and $7.9 billion from specialty medicine. Over half of the revenue in specialty medicine in 2017 was generated by a single branded drug, Copaxone, which is not an opioid. See Teva Pharmaceutical Industries Limited, SEC Form 10-K for the fiscal year ended December 31, 2017, filed on February 12, 2018 ("Teva 2017 10-K"), pp. 8, 62, 68–69.

products" in the U.S. in its annual report for 2006, and 2010 through 2017. None of these annual reports identify an opioid as one of Teva's "most significant generic products."[17]

23. Cephalon is a wholly owned subsidiary of Teva USA's parent company, and was acquired in 2011.[18] As part of the transaction, Teva USA became affiliated with Actiq and Fentora, Cephalon's two branded opioid products.[19] Both products are Transmucosal Immediate-Release Fentanyl ("TIRF") analgesic medicines formulated as lozenges (Actiq) or tablets (Fentora) that deliver the active ingredient, fentanyl citrate, as they dissolve in a patient's mouth over the course of 15–30 minutes.[20] Both drugs are available in multiple dosage strengths to allow individualization of dosing.[21] The primary difference between Fentora and Actiq is the delivery mechanism.[22]

24. Actiq was developed by Anesta Corporation, and approved by the U.S. Food and Drug Administration (FDA) in November 1998.[23] The original indication approved by the FDA stated that:

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[17] Teva 2017 10-K, p. 62; Teva Pharmaceutical Industries Limited, SEC Form 20-F for the fiscal year ended December 31, 2006, filed on February 28, 2007, p.11; Teva 2010 20-F, p. 55; Teva Pharmaceutical Industries Limited, SEC Form 20-F for the fiscal year ended December 31, 2011, filed on February 17, 2012, p. 55; Teva Pharmaceutical Industries Limited, SEC Form 20-F for the fiscal year ended December 31, 2012, filed on February 12, 2013, p. 60; Teva Pharmaceutical Industries Limited, SEC Form 20-F for the fiscal year ended December 31, 2013, filed on February 10, 2014, p. 59; Teva Pharmaceutical Industries Limited, SEC Form 20-F for the fiscal year ended December 31, 2014, filed on February 9, 2015, p. 53; Teva Pharmaceutical Industries Limited, SEC Form 20-F for the fiscal year ended December 31, 2015, filed on February 11, 2016, p. 58; and Teva Pharmaceutical Industries Limited, SEC Form 20-F for the fiscal year ended December 31, 2016, filed on February 15, 2017, p. 61.

[18] Teva Pharmaceutical Industries Ltd. Press Release, "Teva Completes Acquisition of Cephalon," October 14, 2011, available at https://www.tevapharm.com/news/teva_completes_acquisition_of_cephalon_10_11.aspx, accessed on February 14, 2019.

[19] I understand that Actiq and Fentora are the only branded opioid analgesics manufactured by the Teva Defendants. See Teva, "Full Product Catalog," December 27, 2018 ("Teva Full Product Catalog"), available at https://www.tevagenerics.com/products/product-search, pp. 151, 154, accessed on May 10, 2019.

[20] FDA, "Transmucosal Immediate-Release Fentanyl (TIRF) Medicines," July 9, 2015, available at https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm282110.htm, accessed on February 14, 2019; Actiq, "Highlights of Prescribing Information," December 2016, available at http://www.actiq.com/pdf/ActiqDigitalPIandMedGuide.pdf, pp. 1, 3, accessed on February 28, 2019; Fentora, "Highlights of Prescribing Information," December 2016, available at http://www.fentora.com/pdfs/pdf100_prescribing_info.pdf, pp. 1, 3, accessed on May 10, 2019.

[21] Actiq, "Highlights of Prescribing Information," December 2016, available at http://www.actiq.com/pdf/ActiqDigitalPIandMedGuide.pdf, p. 1, accessed on February 28, 2019; Fentora, "Highlights of Prescribing Information," available at December 2016, http://www.fentora.com/pdfs/pdf100_prescribing_info.pdf, p. 1, accessed on May 10, 2019.

[22] Cephalon, Inc., SEC Form 10-K for the fiscal year ended December 31, 2007, filed on February 28, 2008, pp. 8–9.

[23] Under a license agreement with Anesta, Abbott Laboratories launched Actiq in March 1999. On July 17, 2000, Cephalon announced that it had agreed to acquire Anesta, completing the transaction in October of that year. See Anesta Corporation, SEC Form 8-K, filed on March 24, 2000; Rochelle Sharpe, "Medicine for Flare-Ups of Cancer Pain, Anesta's Actiq, is Approved by the FDA," *The Wall Street Journal*, November 6, 1998, available at https://www.wsj.com/articles/SB910283165711912000, accessed on February 14, 2019; "Anesta Corp. Licenses Actiq Rights to Elan / Novel Breakthrough Pain Therapy to Be Marketed by Elan Pharma International," *CTK Protext*, available at http://www.protext.cz/novy/press-release.php?id=1344, accessed on February 14, 2019; Cephalon, Inc. Press Release, "Cephalon and Anesta Announce Merger to Create Stronger, More Profitable Pharmaceutical Business," July 17, 2000, available at http://phx.corporate-ir.net/phoenix.zhtml?c=81709&p=irol-newsArticle&ID=182729, accessed on February 14, 2019; Cephalon, Inc. Press Release, "Cephalon Completes Merger

> "***Actiq* is indicated only for the management of breakthrough cancer pain in patients with malignancies who are <u>already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain</u>**. Patients considered opioid tolerant are those who are taking at least 60 mg morphine/day, 50 µg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer. Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, *Actiq* is contraindicated in the management of acute or postoperative pain. This product **<u>must not</u>** be used in opioid non-tolerant patients. *Actiq* is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. **Patients and their caregivers must be instructed that *Actiq* contains a medicine in an amount which can be fatal to a child. Patients and their caregivers must be instructed to keep all units out of the reach of children and to discard opened units properly (See Information for Patients and Their Caregivers for disposal. instructions.)** [emphasis in original]"[24]

25. The original indication also contained a warning that Actiq "[m]ay be habit forming."[25] The labels were updated over the years to restrict the indication to patients 16 years of age and older and provide additional information on which patients may be considered opioid tolerant.

26. Cephalon acquired Actiq in 2000.[26] It did not promote Actiq until 2001.[27] Furthermore, Actiq has not been promoted since 2006.[28]

27. Cephalon received FDA approval for Fentora in September 2006.[29] By early 2018, Fentora was no longer promoted.[30] The original indication approved by the FDA was the same as the indication approved for Actiq in 2006. Similar to Actiq, Fentora labels were also

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with Anesta," October 10, 2000, available at http://phx.corporate-ir.net/phoenix.zhtml?c=81709&p=irol-newsArticle&ID=182704, accessed on February 14, 2019; Letter from Cynthia McCormick (FDA) to Patricia J. Richards (Anesta Corporation), "NDA 20-747."

[24] The FDA defines breakthrough pain as "pain that comes on suddenly for short periods of time and is not alleviated by a patient's normal pain management plan." FDA, "Actiq©," November 4, 1998, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/1998/20747lbl.pdf, p.1, accessed on February 22, 2019; FDA, "Transmucosal Immediate-Release Fentanyl (TIRF) Medicines," available at https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm282110.htm, accessed on February 14, 2019.

[25] FDA, "Actiq©," November 4, 1998, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/1998/20747lbl.pdf, p. 1, accessed on February 22, 2019.

[26] Cephalon, Inc., SEC Form 10-K for the fiscal year ended December 31, 2000, filed on March 30, 2001, p. 5.

[27] Cephalon, Inc., SEC Form 10-K for the fiscal year ended December 31, 2000, filed on March 30, 2001, p. 5.

[28] Actiq® Risk Management Program – 31st Quarterly Report, TEVA_MDL_A_00283237–64 at TEVA_MDL_A_00283253, March 29, 2007.

[29] FDA, Fentora Approval Letter, September 25, 2006, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2006/021947s000ltr.pdf, accessed on February 22, 2019.

[30] Deposition of John Hassler, November 16, 2018 ("Hassler Deposition"), pp. 43:22-44:1.

updated since its approval. All of the labels for Actiq and Fentora from approval to the current label are presented in Appendix D1.

28. In July 2015, Teva announced that it was acquiring Allergan plc's subsidiaries that sell generic medicines: Watson Pharmaceuticals, Inc., Actavis LLC, and Actavis Pharma Inc., and other affiliates.[31] The transaction was completed in August 2016.[32]

5.2. The regulatory environment related to prescriptions of opioids

29. Opioid prescriptions have been subject to federal and state laws, treatment guidelines, and regulations. The number of opioid prescribing laws and policies have increased over the years. These laws and policies have played an important role in influencing the sale and prescriptions of the Teva and Actavis Generic Defendants' branded and generic opioid products.

5.2.1. Prescriptions of Actiq, Fentora and other generic opioid medicines manufactured by the Teva and Actavis Generic Defendants are subject to stringent FDA regulations

30. All drugs prescribed and sold in the U.S. have to be approved by the FDA.[33] The FDA "ensures that drugs, both brand-name and generic, work correctly and that their health benefits outweigh their known risks," based on "an independent and unbiased review."[34] In particular, as part of the approval process, the FDA evaluates "clinical benefit and risk information submitted by the drug maker," and can impose various safety requirements on the drug's manufacturer including "an FDA-approved drug label, which clearly describes the drug's benefits and risks, and how the risks can be detected and managed."[35] In addition,

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[31] Teva Pharmaceutical Industries Ltd. Press Release, "Teva to Acquire Allergan Generics for $40.5 Billion Creating a Transformative Generics and Specialty Company Well Positioned to Win in Global Healthcare," July 27, 2015, available at https://www.tevapharm.com/news/teva_to_acquire_allergan_generics_for_40_5_billion_creating_a_transformative_generics_and_specialty_company_well_positioned_to_win_in_global_healthcare_07_15.aspx, accessed on February 14, 2019; "Why Teva Paid $40.5 Billion for Allergan's Generic Business," Knowledge@Wharton, August 5, 2015, available at https://knowledge.wharton.upenn.edu/article/why-teva-paid-40-5-billion-for-allergans-generic-business/, accessed on May 10, 2019.

[32] Teva Pharmaceutical Industries Ltd. Press Release, "Teva Completes Acquisition of Actavis Generics," August 2, 2016, available at https://www.tevapharm.com/news/teva_completes_acquisition_of_actavis_generics_08_16.aspx, accessed on February 14, 2019.

[33] FDA, "What Does FDA Inspect?," August 22, 2018, available at https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194888.htm, accessed on February 14, 2019.

[34] FDA, "Development & Approval Process (Drugs)," June 13, 2018, available at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm, accessed on February 14, 2019.

[35] FDA, "Development & Approval Process (Drugs)," June 13, 2018, available at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm, accessed on February 14, 2019. See, e.g., Letter from Ken Nolan (Center for Drug Evaluation and Research) to Patricia J. Richards (Anesta Corporation), "NDA 20-747," January 9, 1998.

since 2007, the FDA has had "the authority to require a Risk Evaluation and Mitigation Strategy ("REMS") from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks."[36] REMS programs typically include a medication guide to alert patients to potential serious adverse events and describe how to safely use the product, a communication plan to inform health care providers about safety risks, and "elements to assure safe use" that describe specific requirements for health care providers and patients to legally prescribe and use the product, respectively.[37] Moreover, the FDA continues to monitor drugs after they are approved and has the authority to send additional information to the public, ask manufacturers to amend the labelling, limit the use of the drug, or withdraw the drug from the market.[38]

31. Actiq and Fentora have been subject to close scrutiny and stringent regulations by the FDA since their approval. In 1998, Actiq was approved with a restricted distribution program to prevent accidental exposure in children (because the product looked like a lollipop), and potential abuse.[39] In 2006, the patient package insert was converted to a medication guide, which is required to be given to each patient when they fill a prescription. This was to "better ensure that each patient prescribed the drug was fully informed of its serious risks."[40]

32. Fentora also was approved with a medication guide and a Risk Minimization Action Plan ("RiskMAP") to reduce misuse and abuse. The medication guide for Actiq and Fentora stated that "[Actiq/Fentora is an] opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death."[41] For Fentora, the RiskMAP notes that "the abuse

[36] FDA, "Approved Risk Evaluation and Mitigation Strategies (REMS)," available at https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm, accessed on February 14, 2019.

[37] FDA, "What's in a REMS?," January 26, 2018, available at https://www.fda.gov/Drugs/DrugSafety/REMS/ucm592636.htm, accessed on February 14, 2019 (For example, "[p]rescribers may be required to become certified and/or take training prior to prescribing the REMS drug.").

[38] FDA, "Drug Approval Process," available at https://www.fda.gov/downloads/drugs/resourcesforyou/consumers/ucm284393.pdf, p. 2, accessed on February 22, 2019.

[39] FDA, "Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse," available at https://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM566985.pdf, accessed on February 22, 2019.

[40] FDA, "Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse," available at https://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM566985.pdf, accessed on February 22, 2019.

[41] "ACTIQ® (AK-tik): (Fentanyl Citrate) Oral Transmucosal Lozenge, CII," *Dailymed*, October 2018, available at https://dailymed.nlm.nih.gov/dailymed/medguide.cfm?setid=90b94524-f913-48b3-3771-7b2fcffd888a, accessed on February 14, 2019; "FENTORA® (fen-tor-a): (Fentanyl) Buccal Tablet, CII," *Dailymed*, September 2018, available at https://dailymed.nlm.nih.gov/dailymed/medguide.cfm?setid=8f549d95-985b-f783-1ebb-ef57bd2ecb05, accessed on February 14, 2019.

liability of opioids is well known" and that "individuals using FENTORA who are not tolerant to opioids are at risk for clinically significant and life-threatening adverse events."[42]

33. In 2009, the FDA informed Cephalon that a REMS was required for Actiq and Fentora.[43] The FDA worked with Cephalon and the other TIRF opioid product manufacturers to approve a single TIRF REMS in December 2011, which was implemented in March 2012.[44] The TIRF REMS program included a number of specific requirements for health care providers, patients, and pharmacies including:

- Health care providers must complete a knowledge assessment and an enrollment form every two years.[45] This knowledge assessment is a multiple-choice test that ensures that doctors know who appropriate TIRF patients are, what types of patients are vulnerable to abuse, how to convert appropriately between different TIRF medicines, how to titrate TIRF medicine for new patients, whether a specific other drug interferes with TIRF medicines, who TIRF medicines could be fatal to, and how to store TIRF medicines.[46]
- Prior to prescribing, health care providers must provide patients with a medication guide and complete and submit a patient-prescriber agreement every two years.[47] By signing the patient-prescriber agreement, the prescriber must acknowledge that he or she understands the indications for which Actiq and Fentora were approved, the contraindications and the types of patients that opioids could be prescribed to. The prescriber must also acknowledge that he or she is aware of and has counseled the patient about the risks, benefits and the appropriate use of these products.[48] Each patient must also acknowledge that he or she has reviewed the medication guide with the prescriber, and must take the product "exactly as [the] prescriber has directed [emphasis in original]" to avoid "serious side effects."[49] In addition, each patient

[42] Cephalon, Inc., "Risk Minimization Action Plan (RiskMAP)," September 19, 2006 (TEVA_MDL_A_00265075–425 at 081–082).

[43] FDA, "Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse," available at https://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM566985.pdf, accessed on February 22, 2019.

[44] FDA, "Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse," available at https://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM566985.pdf, accessed on February 22, 2019.

[45] FDA, "Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS)," August, 2017, available at https://www.accessdata.fda.gov/drugsatfda_docs/rems/TIRF_2017-09-07_REMS_Document.pdf, accessed on February 21, 2019 ("TIRF REMS").

[46] DEA Form Reference ID: 4148977, "The TIRF REMS Access Program: Knowledge Assessment," available at https://www.accessdata.fda.gov/drugsatfda_docs/rems/TIRF_2017-09-07_Knowledge_Assessment.pdf, accessed on February 22, 2019.

[47] TIRF REMS, ¶ II(B).

[48] Deposition of David S. Egilman, April 26, 2019, pp. 667:15–668:11; Expert Report of Professor Edward Michna, J.D., M.D., May 10, 2019, Section V.B; Expert Report of Melanie H. Rosenblatt, M.D., May 10, 2019, Section VIII.

[49] TIRF REMS, ¶ II(B).

must also acknowledge that he or she would not give TIRF products to anyone else, would store TIRF products safely, and would properly dispose TIRF products as soon as they are no longer needed.[50] Appendix D2 presents an example of a patient-prescriber agreement.

- In order to be certified to dispense TIRF products, pharmacies must have an authorized representative complete a knowledge assessment and enrollment form every two years, train all dispensing staff on the risks associated with TIRF products, provide patients with a medication guide, and enable the pharmacy management system to support communication with the TIRF REMS program.[51]

34. In addition to TIRF REMS, the FDA has enforced numerous policies that influence opioid prescribing. These include:

- Specific safety requirements for the drug's manufacturer. For Actiq, these requirements included providing patients with locks for medicine cabinets and using difficult-to-open packaging.[52]
- Black box warning on all immediate acting opioids, including Actiq and Fentora since 2016, highlighting the importance of proper patient selection, dosing and potential for abuse/addiction.[53]
- Open letters, public health advisories, and workshops regarding opioid education.[54]

5.2.2. The DEA restricts distribution of the Teva and Actavis Generic Defendants' opioid medicines

35. The Drug Enforcement Administration (DEA) is a federal law enforcement agency that assigns drugs to a "schedule," ranked from Schedule I through Schedule V. Opioids are Schedule II substances, defined as "drugs with a high potential for abuse, with use

[50] TIRF REMS, ¶ II(B).

[51] TIRF REMS, ¶ II(B).

[52] "FDA OKs 'Narcotic Lollipop'," *CBS News*, December 13, 1999, available at https://www.cbsnews.com/news/fda-oks-narcotic-lollipop/, accessed on February 14, 2019.

[53] Black box warnings first started appearing on medicines in the 1970s, and are the most serious type of warning the FDA offers to drugs that, after having been on the market, pose a significant/life threatening risk, based off observations and clinical studies. See FDA, "A Guide to Drug Safety Terms at FDA," Consumer Health Information Report, November 2012; Nadia Kounang, "FDA Requires 'Black Box' Warning on Painkillers," *CNN*, June 2, 2016, available at https://www.cnn.com/2016/03/22/health/fda-opioid-black-box-warning/index.html, accessed on February 14, 2019; "Black Box Warnings," *drugwatch*, available at https://www.drugwatch.com/fda/black-box-warnings/, accessed on February 28, 2019.

[54] FDA, "Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse," February 13, 2019, available at https://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM566985.pdf, accessed on February 22, 2019.

potentially leading to severe psychological or physical dependence."[55] These substances require a written and signed prescription in order for patients to receive the drug.[56] As fentanyl products, both Actiq and Fentora are controlled in Schedule II of the Controlled Substances Act.[57]

5.2.3. The Teva and Actavis Generic Defendants' opioid medicines are subject to PDMPs

36. PDMPs are "designed to combat the misuse and diversion of opioids by alerting providers of questionable utilization patterns" by collecting data on a patient's prescribing history.[58] At the end of 2013, Medicare started using a monitoring system to identify patients who were potentially misusing opioids based on unusual physician prescribing or pharmacy dispensing behavior and notifying their plans.[59] In response to low initial utilization of the PDMPs by physicians, some states started passing "must access" laws that require physicians to check on a patient's usage before prescribing.[60]

37. Ohio's PDMP is called Ohio Automated Rx Reporting System ("OARRS") and went into effect in 2006. The OARRS secure database is updated with all prescriptions for controlled substances from all Ohio-licensed pharmacies. Drug wholesalers are required to submit monthly data on prescriptions sold to Ohio pharmacies. Pharmacies, physicians, and investigating agencies have access to OARRS, in order to monitor patient use and identify patterns of physician malpractice and overprescribing. Ohio drug courts were also given access to it in November 2017.[61]

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[55] DEA, "Drug Scheduling," available at https://www.dea.gov/drug-scheduling, accessed on February 14, 2019.

[56] DEA, "Practitioner's Manual: An Informational Outline of the Controlled Substances Act," United States Department of Justice Report, 2006, Section 5, p. 19.

[57] DEA, "Fentanyl: (Trade Names: Actiq®, Fentora™, Duragesic®)," October 2018, available at https://www.deadiversion.usdoj.gov/drug_chem_info/fentanyl.pdf, accessed on February 20, 2019.

[58] Thomas C. Buchmueller and Colleen Carey, "The Effect of Prescription Drug Monitoring Programs on Opioid Utilization in Medicare," *American Economic Journal: Economic Policy*, 10(1), 2018, pp. 77-112 at p. 80.

[59] CMS, "Opioid Misuse Strategy 2016," January 5, 2017, available at https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf, accessed on February 22, 2019; Thomas C. Buchmueller and Colleen Carey, "The Effect of Prescription Drug Monitoring Programs on Opioid Utilization in Medicare," *American Economic Journal: Economic Policy*, 10(1), 2018, pp. 77-112..

[60] Thomas C. Buchmueller and Colleen Carey, "The Effect of Prescription Drug Monitoring Programs on Opioid Utilization in Medicare," *American Economic Journal: Economic Policy*, 10(1), 2018, pp. 77-112 at p. 84.

[61] Board of Pharmacy, State of Ohio, "What is OARRS?", available at https://www.ohiopmp.gov/About.aspx, accessed on April 18, 2019.

5.2.4. Ohio state programs monitor prescribing of the Teva and Actavis Generic Defendants' opioid products

38. In 2012 Ohio implemented a "Coordinated Service Program" that flags Medicaid beneficiaries who receive controlled substances from multiple pharmacies and/or prescribers.[62] The program mandates that an individual can only use a single, designated pharmacy to receive Medicaid-covered prescriptions for controlled substances. Any claims submitted to the Department of Medicaid that are not from the designated pharmacy will be rejected. The designated pharmacy can only change if the pharmacy closes, the individual moves, or the pharmacy is no longer able to provide those services. [63]

39. Effective August 2017, Ohio also implemented prescription limits on the use of opiates for temporary acute pain. Specifically, physicians are prohibited from prescribing opiates for more than seven days for adults and five days for minors, unless they provide a specific reason in a patient's medical records. In addition, the total morphine milligram equivalent ("MME") dose cannot exceed an average of 30 MMEs per day. To enforce these new laws, all prescribers are now required to submit a diagnosis on every controlled substance prescription that is submitted to OARRS.[64]

5.2.5. Earlier regulatory intervention may have limited the alleged harm

40. According to Dr. Cutler, the introduction of regulatory measures such as PDMPs around 2010 and other factors resulted in a reduction in the supply of licit opioids,[65] which in turn resulted in some patients substituting to illicit opioids after 2010. This in turn resulted in a rapid increase in illicit opioid mortality rates.[66] However, as Dr. Ketcham explains in his report, the risks associated with prescription opioids were generally well known well before 2010,[67] and if regulators, The State of Ohio and payors had acted earlier, the alleged harm to the Bellwether Counties could have been limited.

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[62] Ohio Bureau of Workers' Compensation Final Rule 4123-6-21.4 ("Coordinated services program"), available at https://www.bwc.ohio.gov/downloads/blankpdf/OAC4123-6-21.4.pdf, accessed on May 10, 2019; Ohio Department of Medicaid, "Information on the Coordinated Service Program," available at https://pharmacy.medicaid.ohio.gov/sites/default/files/2019%20CSP%20Brochure.pdf, accessed on April 18, 2019.

[63] Ohio Department of Medicaid, "Information on the Coordinated Service Program", available at https://pharmacy.medicaid.ohio.gov/sites/default/files/2019%20CSP%20Brochure.pdf, accessed on April 18, 2019.

[64] State of Ohio, "New Limits On Opiate Prescriptions for Acute Pain Will Save Lives and Fight Addition", available at https://mha.ohio.gov/Portals/0/assets/Initiatives/GCOAT/AcutePrescribingLimits_FINAL.pdf, accessed on April 18, 2019.

[65] Cutler Report, ¶ 52.

[66] Cutler Report, ¶ 54.

[67] Ketcham Report, Section IV.

6. THE MARKET SHARE OF THE TEVA DEFENDANTS' BRANDED OPIOID PRODUCTS (ACTIQ AND FENTORA) IN THE BELLWETHER COUNTIES, AND THE MARKETING EXPENDITURE ON GENERIC OPIOIDS MANUFACTURED BY THE TEVA USA AND ACTAVIS GENERIC DEFENDANTS, WERE MINISCULE

41. Plaintiffs claim that the Marketing Defendants' alleged conduct "has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction, overdose, and death from illicit drugs such as heroin."[68] In this section, I show that the market share of Teva Defendants' branded opioid products in the Bellwether Counties was extremely small during the alleged damages period of 2006 to 2018.[69] Furthermore, consistent with industry practice, Teva USA and Actavis Generic Defendants' marketing expenditures on generic opioids was minimal and was limited to pricing and availability of those medicines.

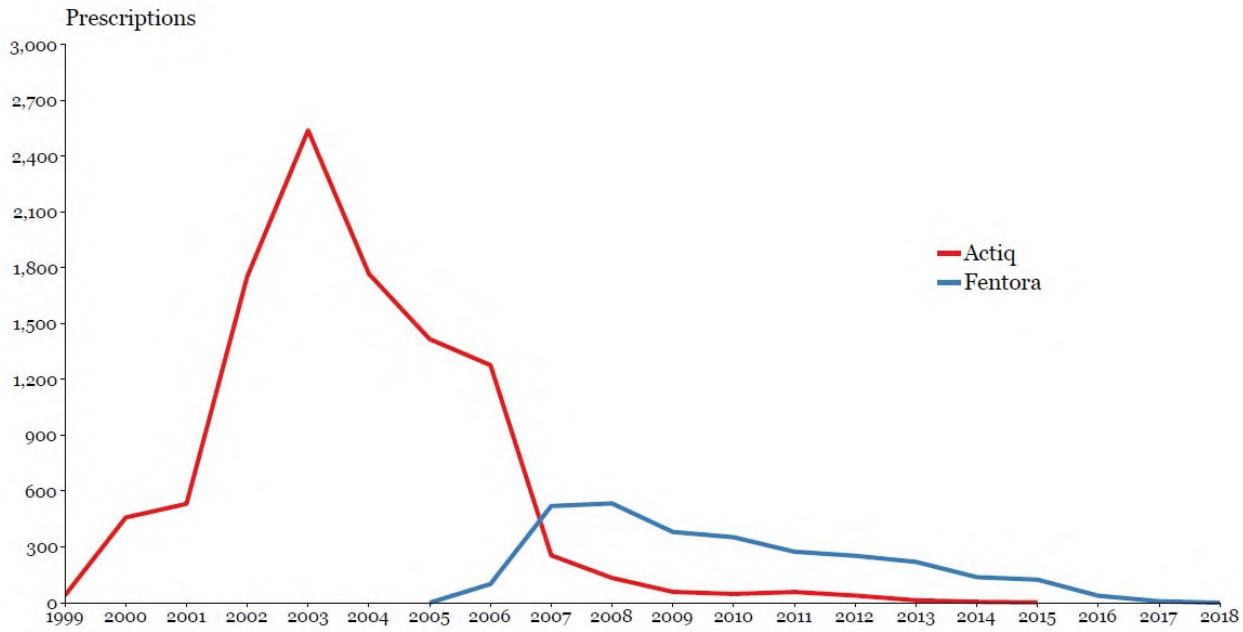
6.1. The market share of the Teva Defendants' branded opioid products in the Bellwether Counties was Minimal

42. Exhibit 1 shows the number of Actiq and Fentora prescriptions (including private health insurance, Medicaid, and all other payors) for the Bellwether Counties.

[68] McGuire Damages Report, ¶ 7.

[69] I note that branded opioids also represented a very small percentage of Teva Defendants' overall prescriptions. In the IMS NPA data produced by Dr. Rosenthal (narme_def_manu_drug_v10), only 0.82% of Teva prescriptions from 1999 to 2017 were for Actiq or Fentora.

EXHIBIT 1
Number of Actiq and Fentora prescriptions for Summit and Cuyahoga counties, 1999 – 2018



Source: IMS Xponent (ALLERGAN_MDL_02485011; ALLERGAN_MDL_03281086; ALLERGAN_MDL_0330303; ALLERGAN_MDL_03320305); HUD-USPS ZIP Crosswalk, Q3 2018

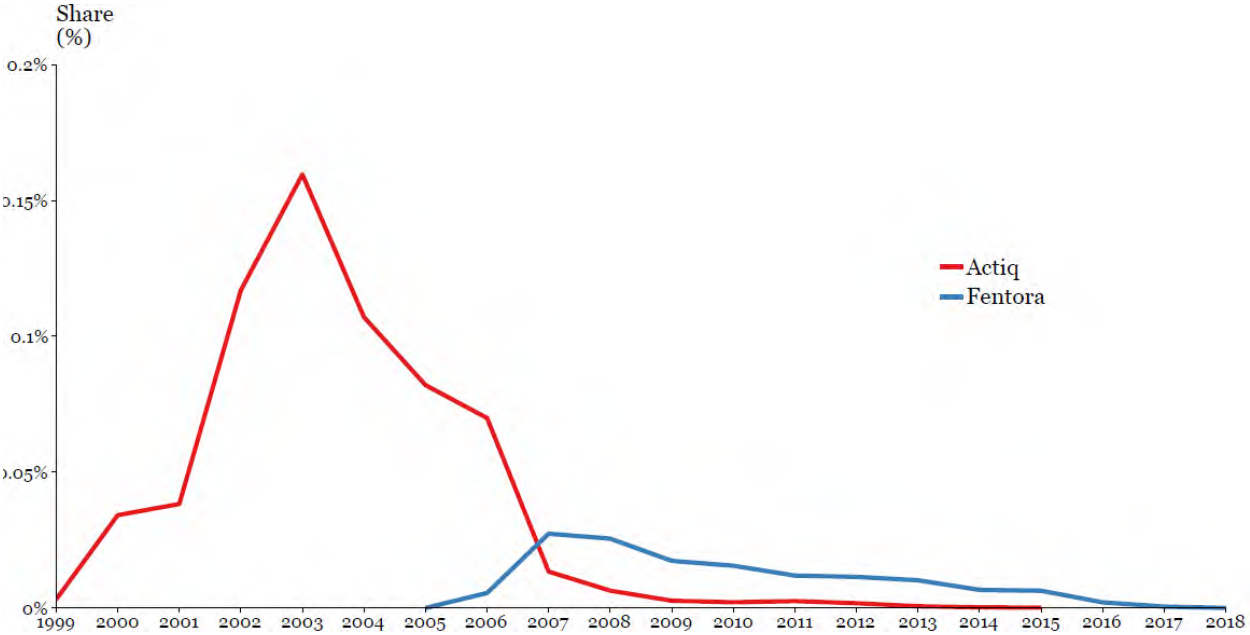
Note: Includes all records for opioids in IMS Xponent Data for which the product group description contains Actiq or Fentora. Prescriptions are apportioned to counties based on the percent of businesses in a zip code that fall within each county; if the total percent of businesses for a zip code is zero, the percent of all addresses is used. Actiq prescriptions peaked in 2003 with 2,539, and Fentora prescriptions peaked in 2008 with 534.

43. Exhibit 2 shows that Actiq prescriptions reimbursed in 2003 represent approximately 0.16 percent of all prescriptions for opioids sold in the Bellwether Counties in that year. Similarly, the fewer than 600 Fentora prescriptions sold in 2008 correspond to approximately 0.03 percent of all prescriptions sold in the Bellwether Counties in that year. In fact, in the IMS Xponent data, Actiq and Fentora made up only 0.02 percent of all opioid prescriptions from 2006 to 2016.[70]

[70] Workpaper 1.

EXHIBIT 2

Actiq and Fentora share of opioid prescriptions for Summit and Cuyahoga counties, 1999 – 2018



Source: IMS Xponent (ALLERGAN_MDL_02485011; ALLERGAN_MDL_03281086; ALLERGAN_MDL_0330303; ALLERGAN_MDL_03320305); HUD-USPS ZIP Crosswalk, Q3 2018

Note: Shares are calculated using all records for opioids in IMS Xponent Data. Drugs are labeled as Actiq or Fentora if the product group description contains Actiq or Fentora. Prescriptions are apportioned to counties based on the percent of businesses in a zip code that fall within each county; if the total percent of businesses for a zip code is zero, the percent of all addresses is used. Actiq's market share peaked in 2003 with 0.16 percent, and Fentora's market share peaked in 2008 with 0.03 percent.

6.2. Consistent with industry practice, Teva USA and Actavis Generic Defendants' promotional spending on generic opioids was minimal and limited to the pricing and commercial availability of those medicines

44. As Dr. Chintagunta's analysis shows, Teva USA and Actavis Generic Defendants' promotional spending on generic opioids was minimal. In particular, he analyzes Dr. Rosenthal's IQVIA data and finds that Teva USA and Actavis Generic Defendants did not incur any promotional spending for 8 of their 14 generic opioid drugs. Additionally, Dr. Chintagunta finds that between January 1995 and May 2018, Teva USA and Actavis Generic Defendants' marketing spending on their Schedule II generic opioid drugs made up less than 0.09 percent of the combined marketing spending by all manufacturers of Schedule II branded and generic opioids.[71]

45. Furthermore, Christine Baeder, Teva USA's Chief Operations Officer for U.S. Generics, noted in her deposition testimony that for Teva USA's "promotion" for its generics drugs is limited to providing information on pricing and "product availability."[72] She also stated that

[71] Chintagunta Report, Section V.C.

[72] Deposition of Christine Baeder, January 24, 2019 ("Baeder Deposition"), p. 417:2–5.

Teva USA does not promote its generic medications, including generic opioids, either to physicians or patients.[73] Baeder also noted that while Teva USA has a "small marketing budget for generics," it is "for support of availability messaging, a limited number of journal advertisements around availability messaging, as well as coupons, programs for some limited generic products where it's deemed appropriate."[74]

46. The same applies to the Actavis Generic Defendants. Several former personnel from the Actavis Generic Defendants testified that they did not promote the safety, efficacy, or therapeutic value of their generic medicines (to physicians or otherwise).[75] For instance, according to Michael Perfetto, former Vice President of Actavis Sales and Marketing, "if you look at generics, we're all the same product. So we use quality, product supply, and pricing primarily to sell our products."[76] Andy Boyer, former Senior Vice President of Actavis Sales and Marketing, further added that "it is physically impossible for a generics company to hire enough sales representatives to go in and speak to physicians about all of [their] generics products."[77] Mr. Boyer also noted that, "We don't detail products . . . [t]hese are not brands, these are generics. We offer up a price and we offer up a consistent supply in our supply chain and hopefully quality products . . . There's no pushing, there's no detailing, there's nothing else there."[78]

47. The limited marketing by Teva USA and Actavis Generic Defendants of their generic opioid products is consistent with industry practice. Specifically, generic sales are not typically driven by a generic manufacturer's marketing efforts. For example, the FDA notes that generic drug manufacturers "generally do not pay for advertising, marketing and promotion," which in part leads to generics being less expensive than brands.[79] The Federal Trade Commission notes that "brand-name and generic marketing strategies are very different… Brand-name drugs are marketed by emphasizing product differentiation to physicians and consumers and by securing favorable formulary placement with PBMs… By contrast, generic drugs are commodity products marketed to wholesalers and drugstores

[73] Baeder Deposition, p. 416:5–18.

[74] Baeder Deposition, p. 417:16–24

[75] See, for example, Deposition of Douglas Boothe, January 17, 2019, pp. 146:21–147:10 (Q. Are you aware of what marketing tools were used by Actavis to drive sales of its generic drugs, including opioids, while you were at the company? … A. …generic drugs generally don't do a lot of marketing."); Deposition of Michael Perfetto, December 18 ("Perfetto Deposition"), 2018, p. 315:11–21 (Q. And what marketing tools did Actavis use to drive sales of these generic products while you were there? A. We – we don't – we don't market products. We sell generics. We don't use marketing. We actually don't use promotion."); Deposition of David Myers, December 13, 2018, p. 48:9–11 ("being a generic company, we don't do major advertising for all products."); p. 83:6–11 ("Watson [Actavis] did not believe in really advertising generic pharmaceuticals.").

[76] Perfetto Deposition, pp. 315:22–316:2.

[77] Deposition of Andrew Boyer, January 15, 2019 ("Boyer Deposition"), pp. 316:24–317:7.

[78] Boyer Deposition, pp. 346:9–17.

[79] FDA, "Generic Drugs Undergo Rigorous FDA Scrutiny," March 27, 2018, available at https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm340343.htm, accessed on February 14, 2019.

primarily on the basis of price."[80] Similarly, in its 2017 10-K SEC filing, Teva USA noted that "physicians and patients have little control over the choice of generic manufacturer, and consequently generic medicines are not actively marketed or promoted to physicians."[81] Indeed, it is the pharmacies that decide which generic drugs to use.[82] This is also consistent with academic research that has shown that physician detailing and product sampling is almost never done for generic products, while journal advertising is occasionally done for generic products, but at a lower rate than for branded products.[83]

48. Rather than relying on marketing, generic drugs generally gain market share over branded drugs primarily through competitive pricing and legislation that encourages the substitution of branded medicines for generic equivalents. In particular:

a. Third party payors ("TPPs") and pharmacy benefit managers ("PBMs") use a variety of tools to steer patients to less expensive generic medicines. One of the most common tools that TPPs and PBMs use are drug formularies, which determine which prescription medicines a particular health plan covers, and how much the patient has to pay out-of-pocket for each medicine.[84] Academic research confirms that the difference in out-of-pocket costs between generic medicines and their reference branded medicines is effective in encouraging patients to switch to generic medicines once they become available.[85] In addition to formularies, TPPs and PBMs often steer patients to generic medicines by imposing requirement of prior authorization on branded medicines or requiring patients to try and fail a treatment with a generic medicine before the insurance plan will cover the use of the reference branded medicine.[86]

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[80] Karen A. Goldman et al., "Authorized Generic Drugs: Short-Term Effects and Long-Term Impact," Federal Trade Commission Report, August 2011, pp. 1-153 at p. 17.

[81] Teva 2017 10-K, p. 5.

[82] Baeder Deposition, p. 416:9–11.

[83] Darius Lakdawalla and Tomas Philipson, "Does Intellectual Property Restrict Output? An Analysis of Pharmaceutical Markets," *Journal of Law and Economics*, 55(1), 2012, pp. 151–187.

[84] Formularies typically organize drugs in tiers, with generic drugs on the lower tiers requiring lower patient co-payments and branded drugs on the higher tiers requiring higher patient co-payments, which can encourage patients to use less expensive generic drugs. See Kaiser Family Foundation and Health Research & Educational Trust, "Employer Health Benefits Annual Survey," 2016, pp. 1-253 at pp. 172–173, 177.

[85] See, e.g., Douglas E. Mager and Emily R. Cox, "Relationship Between Generic and Preferred-Brand Prescription Copayment Differentials and Generic Fill Rate," *The American Journal of Managed Care*, 13(6), 2007, pp. 347–352 at pp. 350–351. See also, Sachin Kamal-Bahl and Becky Briesacher, "How Do Incentive-Based Formularies Influence Drug Selection And Spending For Hypertension?," *Health Affairs*, 23(1), 2004, pp. 227–236 at pp. 227–228, 231.

[86] See, e.g., Ernst R. Berndt, "The U.S. Pharmaceutical Industry: Why Major Growth in Times of Cost Containment?" *Health Affairs*, 20(2), 2001, pp. 100–114 at pp. 102–103; Stanley S. Wallack, Dana Beth Weinberg, and Cindy Parks Thomas, "Health Plans' Strategies to Control Prescription Drug Spending," *Health Affairs*, 23(6), 2004, pp. 141–148 at pp. 141–142, 146.

b. State generic substitution laws are the second major mechanism that promotes the use of generic medicines. Under these laws, pharmacies can substitute generic equivalents for the reference branded medicine unless the physician specifically prohibits generic substitution, usually by writing "dispense as written" on the prescription.[87]

49. In summary, Plaintiffs' allegations that the Teva and Actavis Generic Defendants designed and implemented a sophisticated and deceptive marketing strategy" that "has had severe and far-reaching" consequences is not consistent with the data and deposition testimony. Specifically, Teva USA and Actavis Generic Defendants' marketing efforts with respect to its generic opioid products was miniscule. In addition, data from IMS IQVIA show that the Teva Defendants' branded opioid products' market share in the Bellwether Counties was extremely small.

[87] Ohio Rev. Code Ann. § 4729.38(B) ("Unless instructed otherwise by the person receiving the drug pursuant to the prescription, a pharmacist filling a prescription for a drug prescribed by its brand name may, subject to the following conditions, select a generically equivalent drug, or, in the case of a drug that is a biological product, select an interchangeable biological product").

7. DR. CUTLER'S ESTIMATES OF HARM ATTRIBUTABLE TO PRESCRIPTION OPIOID SHIPMENTS SUFFER FROM METHODOLOGICAL FLAWS, RENDERING HIS FINDINGS UNRELIABLE

50. Dr. Cutler seeks to estimate "the share of various harms imposed on selected departments in each Bellwether government ('Bellwether divisions') that is attributable to defendants' misconduct."[88] Specifically, Dr. Cutler considers three "categories" of harm:[89]

- Crime/Public Safety: Sheriff; Juvenile and County courts; Prosecutor and Public Defenders' Office; and Corrections;
- Children/Family Related: Children and Family Services/Children Services Board; and
- Public Health: Alcohol/Drug/Mental Health Boards and Medical Examiners' Office.

51. In this section, I describe the methodological flaws that render his estimates unreliable. I begin with a brief overview of the framework Dr. Cutler uses for his estimation and then proceed to evaluate his analyses and results.

52. At the outset, I would like to note that any calculations provided in this section are not meant to provide an alternative model or estimates of the impact of the Marketing Defendants' alleged conduct on mortality. Instead, they are meant to illustrate the various reasons why Plaintiffs' damages models and calculations are flawed and unreliable. In the following, I elaborate on the above points.

7.1. Overview of Dr. Cutler's framework

53. Dr. Cutler broadly uses the following framework to evaluate the share of the harms attributable to the Marketing Defendants' alleged conduct:[90]

Share of harms attributable to Marketing Defendants' alleged conduct
= (share of harms attributable to opioids)
× (share of opioid harms attributable to opioid shipments)
× (share of opioid shipments due to Marketing Defendants' alleged conduct)

54. In what follows, I first provide an overview of the flaws in Dr. Cutler's analyses. I then proceed to discuss each of those flaws in greater detail.

[88] Cutler Report, ¶ 9.
[89] Cutler Report, ¶ 20, Table III.1, p. 11.
[90] Cutler Report, ¶ 23.

7.2. Overview of the flaws in Dr. Cutler's analyses

55. Dr. Cutler's analyses suffer from several flaws.

a. Dr. Cutler incorrectly assumes that absent Marketing Defendants' alleged conduct, the Bellwether Counties would have incurred none of the costs associated with the purported opioid-related harms that they estimate.

b. Dr. Cutler's estimates of the "share of harms attributable to opioids," particularly with regards to Crime/Public Safety and Summit County's Coroner's Activity, are unreliable. This is because he does not account for the fact that both crime and deaths can have multiple causes, and some crime and deaths would have occurred even absent Marketing Defendants' alleged conduct.

c. Dr. Cutler assumes, without basis, that the relationship between prescription opioid shipments and mortality is weaker than the relationship between opioid consumption and mortality.[91]

d. Dr. Cutler's estimates of the purported "share of harms attributable to opioid shipments" of the Marketing Defendants are unreliable for several reasons:

    i. Dr. Cutler relies on Dr. Rosenthal's estimates of the share of opioid shipments due to Marketing Defendants' alleged conduct, which I understand are deeply flawed according to Dr. Ketcham's and Dr. Chintagunta's assessment.

    ii. Dr. Cutler's "Approach 1" and "Approach 2" both suffer from significant methodological flaws and ad-hoc/unsubstantiated assumptions, which, as Dr. Cutler admits, introduce a bias in his estimated shipment-mortality relationship.

7.3. Dr. Cutler assumes an incorrect but-for scenario that would have existed in the absence of the Marketing Defendants' alleged conduct

56. Dr. Cutler's approach implicitly assumes that absent Marketing Defendants' alleged conduct, the Bellwether Counties would have incurred none of the harms that he attributes to opioids. This position informs his approaches for calculating the purported impact of the Marketing Defendants' shipments on mortality rates. However, according to the U.S.

[91] Throughout, I will refer to opioid-related mortality rates as "mortality." Where necessary, I will make the distinction between licit mortality and illicit mortality.

Department of Health and Human Services, "[t]he problem of prescription drug abuse and overdose is complex and multi-faceted. The prevalence and type of health consequence varies depending on age, gender, race, ethnicity, geography, socioeconomic factors, and diagnosed medical conditions. There are multiple drivers of the problem, such as provider clinical practices; insufficient oversight to curb inappropriate prescribing; insurance and pharmacy benefit policies; and a belief by young people that prescription drugs are not dangerous, which is associated with increased use."[92]

57. These mechanisms are identified in the academic literature. Several studies find that individuals with certain pre-existing conditions are more likely to misuse opioids once they are prescribed opioids for medically appropriate reasons. For example:

a. Brummett et al. (2017) find that among patients who had not used opioids prior to a surgery, about six percent became "new persistent" opioid users; that is, they were still using opioids three to six months after their surgery.[93] According to the study, this definition of new persistent opioid use is "more conservative than the 3-month definition of long-term postsurgical pain by the International Association for the Study of Pain."[94] Importantly, the study finds that patients who had been smokers or were diagnosed with alcohol or substance abuse, anxiety, or chronic pain conditions such as arthritis before surgery were 25–56 percent more likely to become persistent opioid users.[95]

b. In a related study by Lee et al. (2017), researchers found that the rate of new persistent opioid use was about 10 percent for patients undergoing curative-intent surgery for cancer.[96] The rate was higher for patients who received chemotherapy post-surgery, at more than 15 percent.[97] One of the authors of the study suggests that several factors, such as "the emotional trauma of a cancer diagnosis, pain from invasive procedures and a large care team that

[92] Behavioral Health Coordinating Committee Prescription Drug Abuse Subcommittee, "Addressing Prescription Drug Abuse in the United States: Current Activities and Future Opportunities," U.S. Department of Health and Human Services Report, 2013, pp. 5–6.

[93] Chad M. Brummett et al., "New Persistent Opioid Use After Minor and Major Surgical Procedures in US Adults," *JAMA Surgery*, 152(6), 2017 ("Brummet et al. (2017)"), pp. 1–9 at p. 1.

[94] Brummet et al. (2017), p. 3.

[95] Brummet et al. (2017), p. 6.

[96] Jay Soong-Jin Lee et al., "New Persistent Opioid Use Among Patients with Cancer After Curative-Intent Surgery," *Journal of Clinical Oncology*, 35(36), 2017 ("Jay Soong-Jin Lee et al. (2017)"), pp. 4042–4053 at p. 4042.

[97] Jay Soong-Jin Lee et al. (2017), p. 4042.

may not be coordinating prescriptions," can make cancer patients more vulnerable to opioid misuse.[98]

c. In a more recent study, Oquendo and Volkow (2018) suggest that suicides are likely to account for a substantial share of opioid-related deaths.[99] According to the authors, "data suggest that the true proportion of suicides among opioid-overdose deaths is somewhere between 20% and 30%, but it could be even higher." They note that, "preventing [opioid-overdose] deaths will require a better understanding of the diverse trajectories by which overdoses occur, including the distinction between intentional (suicide) and unintentional (accidental) deaths, be they in patients with chronic pain who overdose on their opioid analgesics or in those with a primary opioid use disorder (OUD)."[100] Dr. Cutler fails to account for the fact that some of those intentional deaths would have occurred even absent the Marketing Defendants' alleged conduct.

58. In summary, Dr. Cutler incorrectly assumes that absent Marketing Defendants' alleged conduct, the Bellwether Counties would have incurred none of the harms that he attributes to opioids. In doing so, Dr. Cutler ignores factors like pre-existing patient conditions and intentional deaths, due to which the Bellwether Counties would have incurred some of the same harms even absent Marketing Defendants' alleged conduct.

7.4. Dr. Cutler's estimates of the share of harms attributable to opioids are unreliable

7.4.1. Crime/public safety

59. To estimate the share of drug-crimes that are opioid-related, Dr. Cutler applies "the share of drugs seized and tested by forensic laboratories in drug crime investigations reported by the National Forensic Laboratory Information System (NFLIS)."[101] Dr. Cutler clarifies that the "opioid share of reported drug crimes is calculated using the share of such

[98] Jessica Webster Sendra, "For 1 in 10 Cancer Patients, Surgery Means Opioid Dependence," *Michigan Health Lab*, November 1, 2017, available at https://labblog.uofmhealth.org/rounds/for-1-10-cancer-patients-surgery-means-opioid-dependence, accessed on February 14, 2019.

[99] Maria A. Oquendo and Nora D. Volkow, "Suicide: A Silent Contributor to Opioid-Overdose Deaths," *New England Journal of Medicine*, 2018, available at https://www.nejm.org/doi/10.1056/NEJMp1801417, accessed on May 10, 2019

[100] Maria A. Oquendo and Nora D. Volkow, "Suicide: A Silent Contributor to Opioid-Overdose Deaths," *New England Journal of Medicine*, 2018, available at https://www.nejm.org/doi/10.1056/NEJMp1801417, accessed on May 10, 2019

[101] Cutler Report, ¶39.

tests undertaken by forensic laboratories in Ohio in which an opioid was detected."[102] He applies this share to the number of drug crimes he estimates in each Bellwether County.[103]

60. Therefore, to the extent multiple drugs were detected in the laboratory tests, it is not appropriate to draw a causal link between opioids and crime. Furthermore, Dr. Cutler does not distinguish between prescription and non-prescription opioids. Dr. Cutler inflates the number of opioid-related drug crimes he estimates in the Bellwether Counties by ignoring crimes that may have been committed due to the non-opioid drug.

7.4.2. Coroner's activity in Summit County

61. To calculate the share of opioid-related overdose cases for Summit County, Dr. Cutler relies on:[104]

- the number of overdose cases where opioids are identified as a cause of death; or
- the number of deaths where drugs or substance abuse has been identified as the cause and an opioid has been detected in the toxicology tests.

62. With respect to deaths in the second category, Dr. Cutler attributes these deaths to opioids even if (i) the death was not exclusively due to opioids (e.g. "Cocaine and oxycodone use");[105] (ii) the death was due to illicit opioids; or (iii) involved multiple or non-specific drug substance abuse (e.g., if the cause of death is "acute and chronic substance abuse", and the toxicology report includes opioids such as oxycodone, but also other substances such as diazepam and nordiazepam).[106]

63. As shown in Exhibit 13 and Exhibit 14 below, an analysis of the CDC Wonder data reveals that between 2006 and 2016, among all deaths that involve opioids, between 19-33% in Cuyahoga County and 8-26% in Summit County also have non-opiate drugs involved. As Dr. Cutler admits,[107] he does not perform any corrections to account for this. To the extent such victims would have died even absent opioid use, Dr. Cutler's model will inappropriately attribute such deaths to Marketing Defendants' alleged conduct.

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[102] Cutler Report, ¶39.

[103] Dr. Cutler admits that he uses numbers from NFLIS reports without making an adjustment. See Deposition of David Cutler, April 26, 2019 ("Cutler Deposition"), pp. 230:16-231:9.

[104] Cutler Report, Appendix III.G.1.

[105] SUMMIT_000087427, see case number 53461.

[106] SUMMIT_000087427, see case number 901567.

[107] Cutler Deposition, pp. 142:1–144:14.

7.5. Dr. Cutler's claim that the impact of shipments on mortality will understate the true impact of prescription opioids on mortality is fundamentally flawed

64. According to Dr. Cutler, "the ideal analysis would relate mortality to consumption [rather than shipments] of prescription opioids [emphasis in original]."[108] However, he notes that "data on consumption in an area are not available, so data on shipments to the area are used as a proxy for consumption."[109] According to Dr. Cutler, "consumption per capita is likely to have been higher than shipments per capita in Ohio,"[110] and on that basis he concludes that, "the estimated relationship between shipments and mortality will understate the relationship between consumption and mortality."[111] Dr. Cutler supports this claim by stating that "[s]tandard econometrics texts recognize that measurement error of this type will result in regression estimates that underestimate the magnitude of the true underlying economic relationships."[112]

65. Dr. Cutler's reasoning is fundamentally flawed. First, he provides no empirical evidence to support his claim that shipments in Ohio are always less than consumption. Even if this were true, the textbook that Dr. Cutler cites to clarifies that even if the variable of interest (e.g., consumption) is always underestimated (e.g., by shipments), it does not necessarily follow that the relationship between the observed variable (shipments) and the outcome (mortality) will be weaker than the relationship between the variable of interest (consumption) and outcome (mortality).[113]

66. Second, when Dr. Cutler states that, "[s]tandard econometrics texts recognize that measurement error of this type will result in regression estimates that underestimate the magnitude of the true underlying economic relationships," [114] he is referring to the concept of "attenuation bias." However, the textbook that Dr. Cutler cites makes it clear that attenuation bias occurs only under the assumption that the measurement error is uncorrelated with the variable of interest (consumption).[115] In other words, there should be no systematic relationship between the extent to which shipments "mis-measure" opioid-consumption and the level of consumption. Dr. Cutler has provided no evidence to support his implicit assumption.

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[108] Cutler Report, ¶ 73.

[109] Cutler Report, ¶ 74.

[110] Cutler Report, ¶ 73.

[111] Cutler Report, ¶ 74.

[112] Cutler Report, ¶ 74.

[113] Jeffrey M. Wooldridge, "Single-Equation Linear Model and Ordinary Least Squares Estimation," Econometric Analysis of Cross Section and Panel Data, (Cambridge, London: The MIT Press, 2010) ("Wooldridge 2010"), pp. 78–80.

[114] Cutler Report, ¶ 74.

[115] Wooldridge 2010, pp. 80–82.

7.6. Dr. Cutler's assumes without basis that the impact of shipments on mortality will accurately measure the impact of opioids on specific harm categories

67. Dr. Cutler uses his estimated impact of shipments on mortality as a proxy for the impact of opioids on his harm categories. In other words, Dr. Cutler assumes that if the Marketing Defendants' shipments account for an estimated x% of incremental opioid-related mortality, then x% of opioid-related harm to Crime/Public Safety, Children/Family Related, and Public Health respectively was due to Marketing Defendants' alleged conduct.

68. Dr. Cutler's position cannot be justified. Even if for a given increase in shipments, mortality increases at a certain rate, Dr. Cutler cannot assume that Crime/Public Safety, Children/Family Related, and Public Health will also increase at the same rate, since they are all affected by several factors independent of shipments (e.g. poverty rates or county budget cuts).

7.7. Dr. Cutler's estimates of the impact of shipments on mortality are flawed and unreliable

7.7.1. Dr. Cutler relies on Dr. Rosenthal's flawed estimates

69. In order to attribute harm to the Marketing Defendants' alleged conduct, Dr. Cutler relies on Dr. Rosenthal's estimates of "excess" shipments attributable to Marketing Defendants' alleged conduct. However, as discussed in the accompanying expert reports by Dr. Ketcham and Dr. Chintagunta, Dr. Rosenthal's results are deeply flawed and unreliable. As a result, Dr. Cutler's estimates of the harms attributable to Marketing Defendants' alleged conduct are flawed and unreliable.

70. Even putting aside this fundamental defect, Dr. Cutler's estimates are unreliable. Specifically, Dr. Cutler uses two approaches to estimate the impact of shipments on harm. I now discuss the flaws and their implications in each of these approaches.

7.7.2. Dr. Cutler's estimates of the impact of shipments on mortality based on his "Approach 1" are unreliable and biased

71. In this section, I describe Dr. Cutler's "Approach 1" for estimating the impact of shipments on mortality rates. I then highlight the flaws in Dr. Cutler's estimates. I first consider his estimates for the 2006–2010 period and then his estimates for the 2011–2016 period.

7.7.2.1. Dr. Cutler's 2006–2010 estimates are unreliable and artificially inflated under "Approach 1"

72. Dr. Cutler estimates the impact of shipments on all mortality using the following "direct regression" model:

$$\Delta M = M_i^{post} - M_i^{pre} = \alpha + \beta_1 S_i + \delta X_i^{pre} + \beta \Delta Z_i + \varepsilon_i$$

where i denotes the county, M is opioid-related mortality, the "pre" period is 1993–95, the "post" period is 2009–2010, S_i is the average shipments per capita per day over the period 1997–2010, and X_i^{pre} is a vector of pre-period averages of mortality rates and demographic and socioeconomic variables. ΔZ_i are changes (post minus pre) in demographic and socioeconomic variables.[116]

73. Then, for each year, t, in the period 2006–2010, he calculates the impact of shipments on all opioid mortality as follows:[117]

$$Impact_t = \left(\Delta M_{actual} - \Delta M_{but-for}\right)_t = \left(M_{actual}^{post} - M_{but-for}^{post}\right)_t = \beta_1 \left(S_{actual} - S_{but-for}\right)_t$$

74. The results from this model are unreliable for several reasons. First, Dr. Cutler's coefficient on shipments is biased and thus unreliable.

- Dr. Cutler acknowledges that mortality is affected by "[t]he "supply side" of the illicit drug marketplace [which] depends on factors such as the presence and sophistication of networks of drug dealers, their ability to increase supply of illegal opioids in response to an increase in demand, and the type of heroin which was being supplied to an area."[118] In addition, factors like pre-existing health conditions (specifically all conditions that need prescription opioid), availability of doctors and level of insurance coverage for pharmaceuticals affect the demand for opioids opioid usage and mortality rates.[119] By not controlling for such factors, the coefficient on shipments in Dr. Cutler's model will be biased.
- Dr. Cutler uses inappropriate variables to control for the effects of demographic factors on opioid-related mortality. For example, he uses age categories that span up

[116] Cutler Report, ¶¶ 66-67, 82, 86-88.

[117] This is a result of the following approach: $\Delta M_{actual} = M_{actual}^{post} - M^{\text{pre}} = \alpha + \beta_1 S_i^{actual} + \delta X_i^{pre} + \beta \Delta Z_i + \varepsilon_i$; $\Delta M_{but-for} = M_{but-for}^{post} - M^{\text{pre}} = \alpha + \beta_1 S_i^{but-for} + \delta X_i^{pre} + \beta \Delta Z_i + \varepsilon_i$. The "impact" is then $\Delta M_{actual} - \Delta M_{but-for} = M_{actual}^{post} - M_{but-for}^{post} = \beta_1 \left(S_{actual} - S_{but-for}\right)$. See Cutler Report, ¶ 106. When calculating the impact for a given year t for both actual and but-for shipments, Dr. Cutler uses the cumulative average of average annual shipments until that year.

[118] Cutler Report, ¶ 71.

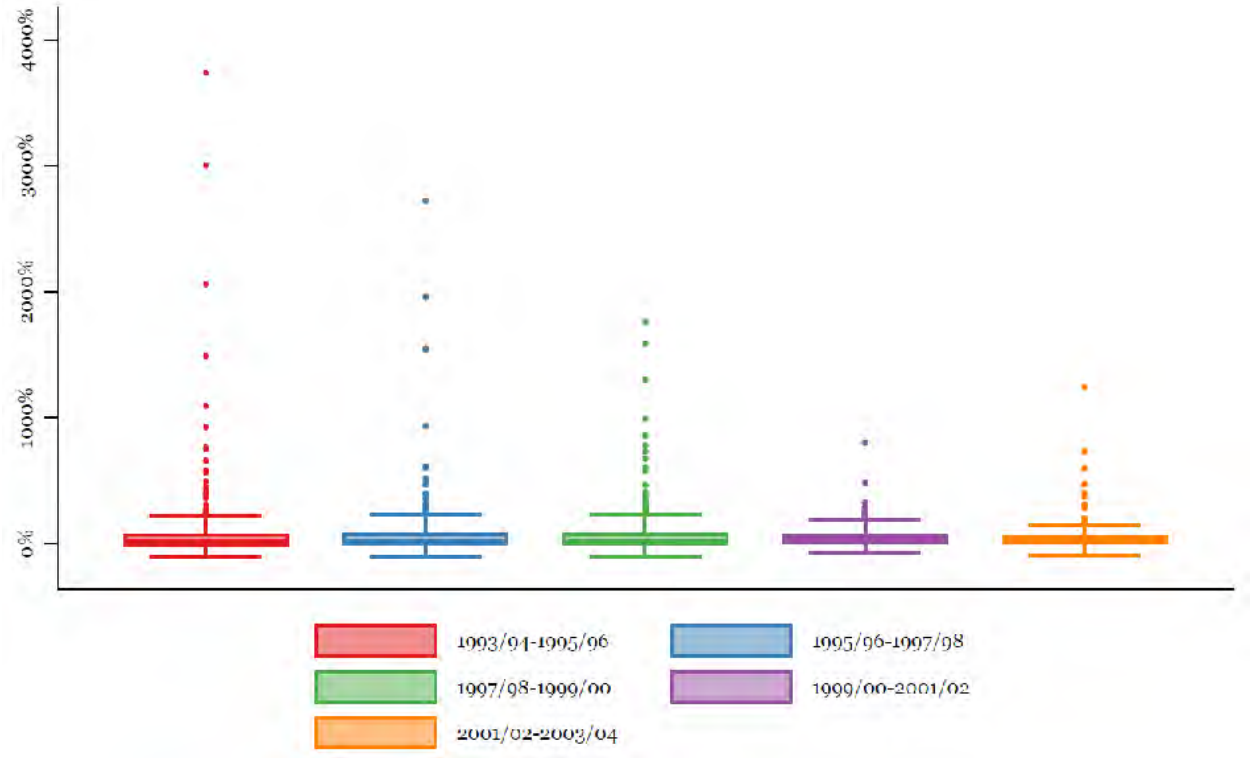
[119] See discussion in Section 7.3 above; Ketcham Report, Section V and Section VII.

to 19 years (e.g. 45-64) as explanatory variables. This can result in what is known as "aggregation bias". To see why, if some counties have a greater proportion of 64-year olds than 45-year olds relative to others, conditioning on a broad age bucket, will not capture the true impact of age on mortality rates. As a result, Dr. Cutler's estimate of the impact of the demographic variables on mortality is unreliable, and therefore his estimate of the impact of shipments on mortality is also unreliable.

75. Second, in performing his analyses, Dr. Cutler does not fully account for limitations and outliers in his mortality data. Exhibit 3 below shows the distribution of the percentage change in county-level opioid-related mortality rates over two-year periods for the following time periods.

- ICD-9 period: 1993/94 to 1995/96 and 1995/96 to 1997/98.
- Change from ICD-9 to ICD-10: 1997/98 to 1999/00.
- ICD-10 period: 1999/00 to 2001/02 and 2001/02 to 2003/04.

EXHIBIT 3
Change in mortality rates



Source: Cutler Production
Note: Mortality rates are Ruhm and ICD-9 adjusted.

76. Looking at the above exhibit, the following become apparent.

a. "Ruhm and ICD-9 adjusted,"[120] county-level mortality rates during the ICD-9 period are unreliable. Specifically, I find that during the ICD-9 period, several counties display abnormal patterns in their mortality rates. For example, the data suggests that between 1995/96 and 1997/98, opioid-related mortality rates more than tripled in 32 counties.[121] In one county (FIPS 20091, which is not displayed in the exhibit for scaling purposes), the data suggest that it increased by more than 277 times.[122] There are far fewer such outliers during the in the "ICD-10 period."

b. Several counties display an abnormal increase in their mortality rates when the coding changed from ICD-9 to ICD-10. For instance, the data suggest that between 1997/98 and 1999/00, opioid-related mortality rates more than tripled in 41 counties and in three counties (FIPS 24510, 24005 and 48215) it increased by more than 13 times.[123] There are far fewer such outliers during the in the "ICD-10 period."

77. Dr. Cutler has provided no analysis to assess the impact of these data limitations and outliers on his results. In fact, the presence of such outliers may inflate the relationship he estimates between shipments and mortality and in turn his impact estimates. To see why, in Exhibit 4 below, I plot the mortality data for FIPS counties 24510 and 24005, the counties with the two largest percentage increases in mortality between 1997/98 and 1999/00.

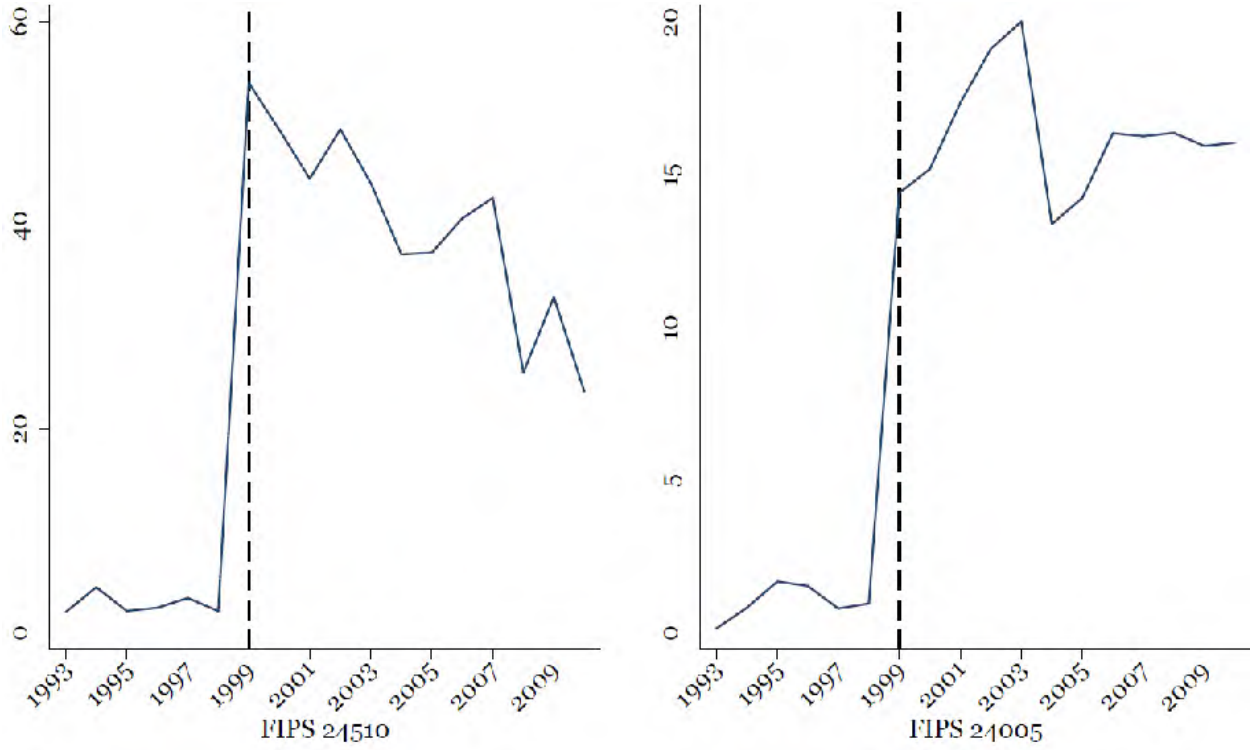
[120] According to Dr. Cutler, "[m]ortality rates are adjusted for changes in coding between ICD-9 and ICD-10 in 1999 and also for underreporting for type of drug in drug-overdose deaths, as in the work of Christopher Ruhm. (Cutler Report, ¶ 82)"

[121] Workpaper 2.

[122] Workpaper 2.

[123] Workpaper 3.

EXHIBIT 4
Opioid-related mortality rates in FIPS counties 24510 and 24005, 1993–2010



Source: Cutler Production
Note: Mortality rates are Ruhm and ICD-9 adjusted.

78. According to the data, in both counties mortality rates remain flat during the ICD-9 period, increase substantially in 1999 (by more than 24 times in FIPS 24510 and 14 times in FIPS 24005).[124] The changes in mortality rates from 2000–2010 are markedly less than the change in 1999. Since Dr. Cutler estimates the relationship between changes in mortality and shipment levels, if in certain counties the pre period mortality rates are artificially low even after Ruhm and ICD-9 adjustments – which seems to be the case for the two examples considered above – the estimated coefficient on shipments will be inflated.

79. Third, Dr. Cutler recognizes that "nearly all of the increase in opioid mortality prior to 2010 is attributable to licit opioid mortality."[125] Yet, he regresses mortality on shipments and does not seek to separately measure the impact of shipments on licit and illicit mortality rates. Considering the different trends in licit and illicit mortality, this is unusual.[126] To highlight the importance of this distinction, I replicate Dr. Cutler's regression separately for

[124] Workpaper 4.
[125] Cutler Report, FN 81.
[126] Cutler Report, Figure III.2 and III.3.

licit and illicit mortality rates using data from 1999 and 2010.[127] The results of these regressions are reported in Appendix E (specifications 3 and 4). I find that the coefficients on shipments (more precisely, average shipments from 1997 to 2010) are 2.74 and 0.72 for licit and illicit mortality, respectively, and they are statistically not equal to each other.[128] The differences between these coefficients are statistically significant at the 95% confidence level. In comparison, when I use 1999/00 as the pre-period in Dr. Cutler's model, the coefficient on shipments is 3.59 Appendix E (specification 2). To be clear, given that none of these models control for the omitted variables discussed above, all of these coefficients are likely to be biased.

80. By making the distinction between licit and illicit mortality, I find that between 2006 and 2010, the impact of shipments on all mortality is between 4.5 and 5.5 percentage points less than what Dr. Cutler estimates (see Exhibit 5 below).[129] As discussed in Sections 8.2.3 and 8.4, the lower impact estimates translate to significant reductions in the alleged damages claimed by Plaintiffs.

81. While I recognize that 1999/00 is six years after what Dr. Cutler seems to implicitly consider to be the "pre-conduct" period, my analysis highlights the importance of estimating the effect of shipments on licit and illicit mortality separately. By not making that distinction, Dr. Cutler seems to be inflating the impact of the Marketing Defendants' alleged conduct on overall mortality.

EXHIBIT 5
Impact estimates when distinguishing between licit and illicit mortality in Dr. Cutler's direct model, 2006–2010

Year	Cutler estimates	Distinguishing between licit and illicit mortality
2006	21.1%	16.6%
2007	22.3%	17.6%
2008	23.3%	18.3%
2009	24.4%	19.2%
2010	25.9%	20.4%

Source: Cutler Production
Notes: Results of the regressions for licit and illicit mortality can be found under specifications (3) and (4), respectively in Appendix E.

[127] 1999 is the first year for which licit and illicit mortality can be distinguished in the data.
[128] Their 95% confidence intervals do not overlap.
[129] Workpaper 5.

7.7.2.2. Dr. Cutler's 2011–2016 estimates are fundamentally flawed and artificially inflated under "Approach 1"

82. In this section I first provide a high-level summary of the different methodologies Dr. Cutler uses for licit and illicit mortality, and then proceed to assess them.

83. Dr. Cutler calculates the impact of shipments on licit mortality from 2011–2016 as follows:[130]

a. He predicts the impact of shipments on all mortality for each year from 2011 to 2016 by multiplying the coefficient on shipments from the direct regression (estimated using pre-2011 data) with the difference between actual and but-for (i.e. absent Marketing Defendants' alleged conduct) cumulative average per capita shipments for 2011–2016.

b. He calculates the ratio of the predicted impact on mortality for a given year and the impact he estimated for 2010.

c. He assumes that in 2010, the impact of shipments on licit mortality would have been the same as the impact he estimates for all mortality (25.9%).

d. For each year from 2006–2011, he inflates the impact calculated in 'c' by applying the ratios calculated in 'b'.

84. To estimate the impact of shipments on illicit mortality from 2011–2016, Dr. Cutler motivates his approach as follows: "after 2010 declines in shipments of prescription opioids generated increased demand for illicit opioids and rapid increases in deaths due to illicit opioids. These events fundamentally altered the relationship between shipments of prescription opioids to an area and opioid-related mortality."[131] He goes on to state that "the increase in deaths due to illicit opioid use after 2010 depends not just on the increase in demand for illicit opioids due to the decline in supply of prescription opioids, but also on the supply of illicit opioids in an area."[132] Citing this, Dr. Cutler uses an "indirect regression" model that takes the following specification:

$$Opioid\ Mortality\ Rate_i^{Pre} = X_i^{Pre}\beta + \epsilon_i$$

[130] Cutler Report, ¶ 109–110.
[131] Cutler Report, ¶ 69.
[132] Cutler Report, ¶ 70.

where the "pre" period is 2008–2010 and X_i^{pre} is a vector of the 2008–2010 averages of various economic and demographic variables.[133]

He then proceeds as follows:[134]

a. He first calculates the illicit mortality attributable to the Marketing Defendants' shipments in 2010 to be 0.81. Based on this, he determines the predicted mortality in 2010.

b. He estimates the indirect regression model using 2008–2010 averages of illicit mortality and the respective averages of economic and demographic variables, and obtains the predicted "baseline" illicit mortality rates for 2010–2016.

c. He calculates the ratio of the 2011–2016 predicted mortalities relative to the 2010 predicted mortality. He applies these ratios to the 2010 predicted mortality calculated in 'a' to obtain predicted illicit mortality rates values for 2011–2016.

d. He calculates the difference between the actual and predicted mortalities from step 'c'.

e. He computes the difference between the excess mortalities calculated in 'd' and the 2010 value calculated in 'a' (these reflect the "incremental mortalities" relative to the 2010 mortalities that Dr. Cutler attributes to the Marketing Defendants' alleged conduct).

f. He applies the weights from Dr. Rosenthal to the differences calculated above and adds the 2010 value calculated in 'a'.

85. There are several problems with Dr. Cutler's analysis. First, Dr. Cutler's modeling framework and shipment data do not support the proposition that counties with high levels of opioid shipments saw a substantial increase in illicit opioid-related deaths. In particular, Dr. Cutler notes that "the increase in deaths due to illicit opioid use is closely related to the growth in demand for illicit drugs after 2010."[135] To support this point, he presents his analysis of heroin mortality rates in Figure III.4 of his report to conclude that "the

[133] Cutler Report, ¶ 77.
[134] Cutler Report, ¶¶ 111-114, Table III.12.
[135] Cutler Report, ¶ 63.

acceleration in heroin mortality is significantly larger in the high shipment counties [compared to low shipment counties]."[136]

86. Dr. Cutler directly contradicts this point in his deposition testimony when he states that "[o]ne of the very interesting things is that there does not seem to be a differential trend in the heroin death rate in areas where opioid shipments were higher versus areas where they were lower, so those trends are very similar trends."[137] Moreover, his own direct regression framework does not support the point. In particular, I assess whether the data and the modelling framework Dr. Cutler relies upon are capable of explaining the impact of pre-2011 shipments on post-2010 mortality rates, by applying his direct regression framework as follows:

$$\Delta \text{illicit}M_i = \text{illicit}M_i^{post} - \text{illicit}M_i^{pre} = \alpha + \beta_1 S_i + \delta X_i^{pre} + \beta \Delta Z_i + \varepsilon_i$$

where the "post" period is 2015/16; the "pre" period is 2009/10; S_i is the average shipments from 1997–2010; X_i^{pre} is a vector containing averages of economic and demographic variables and mortality in the pre period; and ΔZ_i are changes in averages of economic and demographic variables between 2009/10 and 2015/16. The results of this regression are reported in Appendix E (specification 5). I find that the coefficient on shipments is positive, but insignificant. Thus, Dr. Cutler's own framework does not support the basis for assigning any harms due to illicit mortality to the Marketing Defendants' alleged conduct for the 2011–2016 period.

87. Second, Dr. Cutler makes the flawed assumption that the relationship between shipments and mortality that existed pre-2010 will continue to hold post-2010. This contradicts the following statement by Dr. Cutler:

> ". . . after 2010 declines in shipments of prescription opioids generated increased demand for illicit opioids and rapid increases in deaths due to illicit opioids. These events fundamentally altered the relationship between shipments of prescription opioids to an area and opioid-related mortality [emphasis added]."[138]

88. Effectively, Dr. Cutler estimates a relationship between two variables for one time period and then relies on that estimated relationship in a subsequent time period even though, in his own words that relationship does not hold any more. Dr. Cutler attempts to explain away this contradiction between his model and the text of his report by claiming in his deposition

[136] Cutler Report, ¶ 60. Dr. Cutler defines high shipment and low shipment to be counties in the upper and lower quartile in terms of the shipments of prescription opioids from 1997–2010.

[137] Cutler Deposition, p. 415:17–22.

[138] Cutler Report, ¶69.

that the 2010 structural change would affect only illicit mortality post-2010.[139] As a result, Dr. Cutler takes the implausible position that the relationship between shipments and mortality would remain the same after 2010 even though the relationship between shipments and licit mortality and between shipments and illicit mortality would be different. In light of this flaw, his estimates of the impact of shipments on licit mortality for 2011–2016 are flawed and unreliable.

89. Third, having estimated the indirect regression above, Dr. Cutler attributes a portion of the estimated increase in illicit mortality that cannot be explained by his economic and demographic variables to the Marketing Defendants' alleged conduct. This is inappropriate given that Dr. Cutler assumes without basis that the relationship between economic and demographic variables and mortality will remain the same over time. Furthermore, as discussed in the context of the direct model, there are several factors, particularly on the supply side, which Dr. Cutler does not control for. Dr. Cutler recognizes this when he states that "[t]he indirect regression attributes the entirety of unexplained opioid-related mortality to shipments. To the extent that other factors not modelled in the 'baseline' regression contributed to increases in opioid mortality, the indirect approach has the potential to overstate the impact of defendants' actions."[140] In his deposition, Dr. Cutler acknowledges some variables such as eligibility of employer-sponsored health insurance, cancer incidence, or mental health issues, could be omitted variables in his regressions.[141] His indirect regression therefore likely suffers from omitted variable bias,[142] and is therefore unreliable.

90. Fourth, Dr. Cutler assumes that in 2010, opioid shipments would have had the same impact on mortality attributable to licit drug use as mortality attributable to both licit and illicit drug use (see paragraphs 83.c and 84.a above). However, the available data suggests that may not be true: In 2010, the estimated impact of shipments on licit and illicit mortality was 24.1% and 12.8% respectively, rather than the 25.9% Dr. Cutler assumes.[143] Exhibit 6 below shows the effect of using the impact of shipments on licit mortality and illicit mortality estimated separately to obtain the impact of shipments on overall mortality in 2011–2016.

[139] Cutler Deposition, pp. 536:16–538:4.
[140] Cutler Report, FN 53.
[141] Cutler Deposition, pp. 501:18–502:16; 502:18–503:13; 503:22–504:19.
[142] Cutler Report, FN 53.
[143] Workpaper 5.

EXHIBIT 6
Impact estimates when distinguishing between licit and illicit mortality in Dr. Cutler's direct model, 2011–2016

Year	Cutler estimates	Distinguishing between licit and illicit mortality
2011	27.9%	23.4%
2012	33.0%	28.5%
2013	37.4%	33.2%
2014	41.5%	37.7%
2015	45.4%	42.1%
2016	47.7%	44.9%

Source: Cutler Production

Note: Results of the regressions for licit and illicit mortality can be found under specifications (3) and (4), respectively in Appendix E.

91. Under my alternative approach, the estimated impact is 2.8 to 4.6 percentage points less than what Dr. Cutler estimates.[144] As discussed in Sections 8.2.3 and 8.4, these differences translate to significant reductions in the damages claimed by Plaintiffs.

92. Fifth, in running his indirect regression, Dr. Cutler assumes that changes in economic and demographic variables will impact mortality rates instantaneously (i.e., during that same period). However, this need not be true. In fact, by using lagged versions of these variables I am able to fit the data just as well as Dr. Cutler. The results of this regression are reported in specification (1) in Appendix F. In addition, as seen Exhibit 7 below, the resulting impact estimates are up to 18 percentage points lower than Dr. Cutler's estimates across the years 2011–2016. As discussed in Sections 8.2.3 and 8.4, this translates to significant reductions in the alleged damages claimed by Plaintiffs.

EXHIBIT 7
Impact estimates when using lagged independent variables in Dr. Cutler's indirect model, 2011–2016

Year	Cutler estimates	Using lagged independent variables
2011	31.5%	27.4%
2012	36.7%	18.6%
2013	40.8%	24.1%
2014	44.6%	32.8%
2015	47.3%	39.3%
2016	49.1%	44.0%

Source: Cutler Production

Notes: Lagged independent variables are based on the years 2005–2007. Adjusted R-squared increases from 0.31 to 0.32. The results of this regression can be found under specification (1) in Appendix F.

93. Finally, Dr. Cutler takes the unusual approach of applying the share of shipments allegedly attributable to the Marketing Defendants' alleged conduct (estimated by Dr.

[144] Workpaper 5.

Rosenthal) only to the incremental mortality rates over and above 0.81.[145] That is, he assumes that the Marketing Defendants' shipments until 2010 would have increased mortality rates by 0.81 for each year from 2011 to 2016 even if no prescription opioids had been sold in that year. Dr. Cutler provides no justification for this assumption. Such an assumption is untenable given that in the period between 2010-2016, there were a wide range of programs and policies that focused on tackling the effects of the opioid abuse epidemic including the Cuyahoga County Opiate Task Force and the Summit County Opiate Task Force. For example, the 2014 Cuyahoga County Opiate Task notes that "The Cuyahoga County Opiate Task Force … has played a significant role in bringing people together to help fight this growing public health epidemic and reduce the number of deaths [emphasis added]."[146] Similarly, in their 2014 report, the County of Summit ADM board adopted a "comprehensive community-based approach inclusive of multiple community organizations, service / treatment providers, law enforcement, court systems, family members and interested parties to address many facets of the opiate / heroin epidemic, including prevention, treatment, recovery supports and other life-saving interventions [emphasis added]."[147]

94. This ad-hoc assumption is a significant component of Dr. Cutler's impact estimates. To illustrate the significance of this assumption, for each from 2011-2016, I apply Dr. Cutler's share of shipments purportedly attributable to the Marketing Defendants' alleged conduct to the difference between the baseline and actual illicit mortality rates.[148] I do so in conjunction with using lagged independent variables in the indirect regression as discussed above. I find that Dr. Cutler's estimates are reduced by between 4.8 and 10.8 percentage points which, as shown below, has significant implications for the damages estimates.

95. Exhibit 8 below provides an overview of the changes to Dr. Cutler's estimates of the impact of the Marketing Defendants' alleged conduct on mortality rates when applying the sensitivities discussed so far. In the Exhibit, Column A shows Dr. Cutler's impact estimates. Column B shows impact estimates when applying Dr. Rosenthal's (flawed) shares to the difference between the baseline and actual illicit mortality rates (as discussed in paragraph 93 above). Column C shows impact estimates when I apply the Column B sensitivity and distinguish between licit and illicit mortality.

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[145] Specifically, he assumes that in 2010, the impact of shipments on illicit mortality would have been 25.9% (i.e., the same as their impact on all mortality). This translates to an impact on illicit mortality of 0.81 (25.9% × 3.14).

[146] Cuyahoga County Opiate Task Force, "Cuyahoga County Opiate Task Force Report 2014," 2014 at p. 3, available at http://opiatecollaborative.cuyahogacounty.us/pdf_OpiateCollaborative/en-US/CC_OpiateTaskForceReport.pdf, accessed on May 10, 2019.

[147] County of Summit ADM Board, "2014 Report to the Community," 2014, at p. 1, available at https://www.admboard.org/Data/Sites/25/2014-annual-report-final.pdf, accessed on May 10, 2019.

[148] Dr. Cutler's share of shipments purportedly attributable to the Marketing Defendants' alleged conduct for a given year are based on Dr. Rosenthal's estimates.

EXHIBIT 8
Impact estimates after applying sensitivities to "Approach 1", 2006–2016

	(A)	Independent variables lagged in indirect model (B)	(C)
Year	Cutler estimates	Applying Rosenthal shares to overall difference in mortality	Applying Rosenthal shares to overall difference in mortality and distinguishing between licit and illicit mortality in direct model
2006	21.1%	21.1%	16.6%
2007	22.3%	22.3%	17.6%
2008	23.3%	23.3%	18.3%
2009	24.4%	24.4%	19.2%
2010	25.9%	25.9%	20.4%
2011	27.9%	23.2%	20.1%
2012	33.0%	22.7%	18.7%
2013	37.4%	26.7%	22.7%
2014	41.5%	32.3%	28.9%
2015	45.4%	38.0%	35.1%
2016	47.7%	42.0%	39.7%

Source: Cutler Production

96. To be clear, none of the sensitivities presented above should be taken as alternative impact estimates. They simply serve to highlight the flaws and general unreliability of Dr. Cutler's estimates, rendering them invalid. Nevertheless, as discussed in Sections 8.2.3 and 8.4 below, the effect of these sensitivities on the Plaintiffs' damages figures can be substantial.

7.8. Dr. Cutler's estimates of the impact of shipments on mortality based on his "Approach 2" are completely unreliable

97. In his Approach 2, Dr. Cutler regresses the same indirect regression described above, but using 1993–95 data.[149] Dr. Cutler then attributes a portion of all incremental mortality that cannot be explained by his economic and demographic variables to the Marketing Defendants' alleged conduct. This is inappropriate for the same reasons discussed in paragraphs 74 and 89.

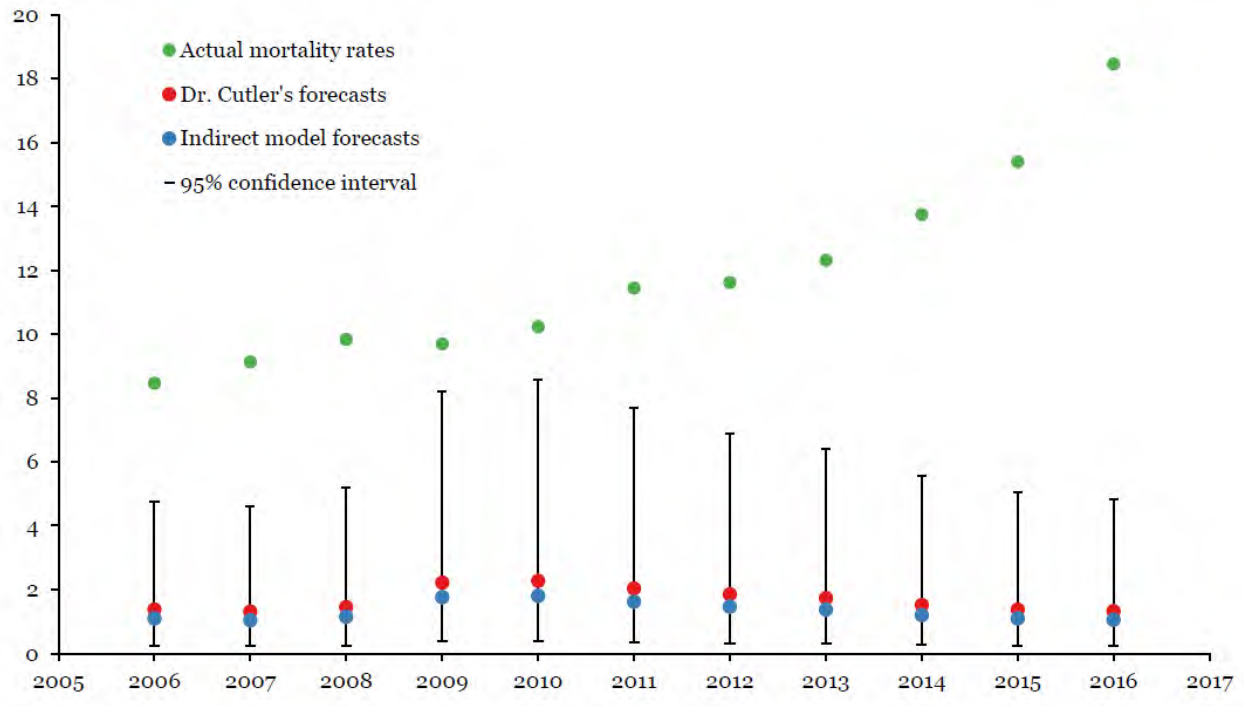
98. A further problem with Dr. Cutler's Approach 2 is that he uses the relationship between economic and demographic variables estimated from a cross-sectional model to forecast mortality rates 20 years (1996 to 2016) into the future, during which time he has himself acknowledged that there have been significant changes in the relationship between opioid shipments and mortality rates.

99. In addition, the model does not take into account numerous other factors that evolve over time and also affect mortality rates, such as, but not limited to eligibility of employer-sponsored health insurance, cancer incidence, or mental health issues, could be omitted

[149] Cutler Report, ¶ 116.

variables in his regressions.[150] Dr. Cutler cannot simply assume that such factors do not matter over a 20 year period. Indeed, as seen in Exhibit 9 below, the predictions from Cutler's indirect model come very large margins of error attached to them. Dr. Cutler's predictions (red dots) are marginally greater than the model's predictions (blue dots) because in his code he allows for a small positive "error" in the model's forecast. Nevertheless, it is clear that the 95% confidence intervals are substantial. Dr. Cutler fails to appropriately account for this significant uncertainty in his Approach 2 estimates and as such they are unreliable.

EXHIBIT 9
Mortality rate forecasts under "Approach 2", 2006–2016



Source: Cutler Production

Notes: Confidence intervals are for the indirect model's forecasts. In order to generate out of sample prediction errors, the regression was run under the assumption of homoscedastic standard errors. Dr. Cutler's predicted values are greater than the indirect model predictions because in his code, he adds a "Mean Squared Error/2" term when computing forecast values.

100. Dr. Cutler does not take into account the full extent of this uncertainty in his impact calculations under Approach 2. In particular, given the significant margins of error attached to his indirect model's forecasts, his impact estimates, which rely on the difference between the actual and forecast mortality rates, may also be significantly inflated.

101. In summary, Dr. Cutler's results (i) rely on Dr. Rosenthal's deeply flawed results; (ii) rely on several ad-hoc and contradictory assumptions; (iii) are likely affected by outliers; and

[150] Cutler Deposition, pp. 501:18-502:16; 502:18-503:13; 503:22-504:19.

(iv) suffer from severe methodological flaws. Thus, his estimates of the purported impact of Marketing Defendants' alleged conduct on mortality rates cannot be relied upon.

8. DR. MCGUIRE HAS SUBMITTED TWO REPORTS THAT CONTAIN SERIOUS CONCEPTUAL AND METHODOLOGICAL ERRORS THAT INFLATE HIS DAMAGE ESTIMATES

102. Dr. McGuire has submitted two reports where he estimates that the Bellwether Counties in aggregate suffered (i) a "net economic burden" supposedly amounting to $20.1 billion between 2006-2016 due to "public nuisance;"[151] and (ii) $194.4 million in purported damages due to costs incurred by Bellwether government departments between 2006 and 2018.[152] For the sake of simplicity, I will refer to both of these estimates as "damages."

103. The rest of this section proceeds as follows: In Section 8.1, I provide an overview of Dr. McGuire's approach in each of his two reports. In Section 8.2, I discuss some overarching conceptual and methodological errors in his analyses. In Section 8.3, I elaborate on specific errors in Dr. McGuire's calculations. In Section 8.4, I provide a summary of the impact of my critiques of both Dr. McGuire and Dr. Cutler's analyses to illustrate how Dr. McGuire overstates damages. In Section 8.5, I discuss why Dr. McGuire's damages estimates are not informative from the perspective of quantifying the purported damages, if any, that the Defendants are allegedly liable for.

104. At the outset, I would like to note that any calculations provided in this section are not meant to provide alternative estimates of damages. Instead, they are meant to illustrate the various reasons why Dr. McGuire's damages models and calculations are flawed and unreliable.

8.1. Overview of Dr. McGuire's approaches

105. In his Public Nuisance Report, Dr. McGuire attempts to quantify the supposed harms under the following five groups: mortality, morbidity, babies born with neonatal abstinence syndrome ("NAS"), crimes and child maltreatment.[153] He also includes damages incurred by the Cuyahoga and Summit County governments ("Bellwether Governments"), which he calculates in the McGuire Damages Report.[154] Dr. McGuire's estimates are reproduced in Exhibit 10 below.

[151] McGuire Public Nuisance Report, ¶ 15 and Table 1.
[152] McGuire Damages Report, ¶ 11 and Table IV.2.
[153] McGuire Public Nuisance Report, ¶ 11.
[154] McGuire Damages Report, ¶ 11 and ¶¶ 133–134.

EXHIBIT 10
Dr. McGuire's estimates of alleged harms due to opioid medicine shipments, 2006–2016 (millions)

Form of Harm	Method of Valuation	Cuyahoga	Summit	Total
Mortality: Deaths	Value of statistical life (VSL)	$11,279	$5,377	$16,656
Morbidity: OUD Cases	Elevated health care costs	$1,376	$587	$1,963
Babies with NAS	Elevated health care costs	$9	$7	$16
Crimes	Valuation	$327	$126	$453
Child Maltreatment	Elevated costs	$401	$297	$698
Bellwether Government Costs	Elevated costs	$172	$99	$271
Totals		***$13,564***	***$6,492***	***$20,056***

Source: Table 12 from McGuire Public Nuisance Report
Note: These numbers are based on the share of harm attributable to all opioid shipments estimated by Dr. Cutler under Approach 1, which he refers to as the "direct approach." These shares are presented in Appendix III.I Table I.4 of the Cutler Report.

106. For each of the five harm groups, Dr. McGuire quantifies the total value of the alleged opioid-related harms by multiplying his estimates of the number of instances of the relevant harm with an estimated dollar value per instance of that harm. To this product, he applies the share of opioid-related harm attributable to all opioid shipments as estimated in the Cutler Report.[155]

Harms due to all opioid shipments between 2006-2016
= (Share of opioid-related harm attributable to all opioid shipments)
× (Instances of harms that are opioid-related)
× (Valuation of a harm instance)

107. For example, in calculating mortality costs, Dr. McGuire first estimates the number of opioid-related deaths and then applies the share of harm attributable to all opioid shipments as estimated in the Cutler Report.[156] He monetizes the resulting number of deaths by using a value of statistical life ("VSL") as the valuation method for each death.[157]

[155] Cutler Report, Appendix III.I Table I.4. As discussed in Section 7.7 above, Dr. Cutler's analyses suffer from several flaws that render his estimates unreliable.
[156] McGuire Public Nuisance Report, ¶ 46.
[157] McGuire Public Nuisance Report, ¶ 113.

108. In his Damages Report, Dr. McGuire estimates the supposed damages suffered (in the form of costs incurred) by the Bellwether Governments. His estimates are presented in Exhibit 11 below.

EXHIBIT 11
Dr. McGuire's estimates of alleged damages to Bellwether Governments in dollars, 2006–2018 (millions)

	Total
Approach 1	
Cuyahoga County	$125.5
Summit County	$68.8
Total	**$194.4**

Source: Table IV.2 from McGuire Damages Report
Note: These numbers are based on the share of harm attributable to the Marketing Defendants' alleged conduct estimated by Dr. Cutler under Approach 1, which he refers to as the "direct approach." These shares are presented in Table III.13 of the Cutler Report.

109. To estimate these costs, Dr. McGuire first identifies government divisions that may have been affected by the opioid abuse crisis.[158] For each division, he considers the total costs (expenses) and identifies the share that would be affected in dealing with the opioid abuse crisis.[159] To estimate the latter, he multiplies the total cost base with the share of opioid-related activities estimated in the Cutler Report.[160] Finally, he multiplies that value by the share of harm attributable to the Marketing Defendants' alleged conduct,[161] also as estimated in the Cutler Report.[162] The sum across all affected divisions yields the damages related to the excess costs Bellwether Governments incurred.

Damages due to Marketing Defendants' alleged conduct between 2006-2018
= (Share of opioid-related harm attributable to Marketing Defendants' alleged conduct)
× (Share of activities that are opioid-related)
× (Total costs in dealing with the opioid abuse crisis)

110. For example, in calculating damages related to the Cuyahoga Sheriff's division, Dr. McGuire first reviews costs to obtain an estimate of the total amount that may have been affected by the opioid abuse crisis. He calculates total costs attributable to opioid-related activity by applying the share of opioid-related damages from the Cutler Report to this cost

[158] McGuire Damages Report, ¶ 9.
[159] McGuire Damages Report, ¶ 10.
[160] Cutler Report, Section IV.
[161] McGuire Damages Report, ¶ 11.
[162] Cutler Report, Table III.13. As discussed in Section 7.7 above, Dr. Cutler's analyses suffer from several flaws that render his estimates unreliable.

base. Excess costs are determined by further applying the share of harm attributable to the Marketing Defendants' alleged conduct, as contained in the Cutler Report.[163]

111. As described in Sections 7.7 and 7.8, Dr. Cutler has estimated share of harm figures using Approach 1 and Approach 2, which he refers to as the "direct approach" and "indirect approach," respectively.[164] Dr. McGuire has calculated damages figures using the share of harm estimates using both of these estimates.[165] However, in the text of the Public Nuisance Report, he presents damages calculated using estimates only from Approach 1 as inputs because they yield "more conservative calculations," and relegates the damages calculated using estimates from Approach 2 to the appendix.[166] I focus my attention in this report on critiquing Dr. McGuire's harm estimates based on Dr. Cutler's Approach 1—which are unreliable. The share of harm figures that Dr. Cutler estimates under Approach 2 are unreliable and are subject to additional concerns discussed above in Section 7.8. Therefore, I do not repeat Dr. McGuire's damages calculations using these erroneous alternative share of harm estimates.

8.2. Dr. McGuire commits overarching conceptual and methodological errors

112. Dr. McGuire commits several overarching conceptual and methodological errors in his reports. In what follows, I discuss these in turn.

8.2.1. Dr. McGuire's methodologies have inconsistencies between the two reports

113. There are two differences in the methodologies that Dr. McGuire uses in his two reports. The first difference relates to the time period that Dr. McGuire uses in his analysis. The McGuire Damages Report is restricted to 2006-2016, while the McGuire Public Nuisance Report is based on a longer time period covering 2006-2018.[167] The second difference relates to a common input to both reports, which is the estimated share of opioid-related harm taken from the Cutler Report. In his two reports, Dr. McGuire uses different estimates:

- In the McGuire Public Nuisance Report, he uses harm attributable to all opioid shipments;[168] while

[163] McGuire Damages Report, ¶ 17.
[164] Cutler Report, ¶ 26.
[165] McGuire Damages Report, ¶ 72; McGuire Public Nuisance Report, ¶ 45.
[166] McGuire Public Nuisance Report, ¶ 45; McGuire Public Nuisance Report, Appendix I.
[167] McGuire Damages Report, ¶ 11; McGuire Public Nuisance Report, ¶ 15.
[168] McGuire Public Nuisance Report, FN 57.

- In the McGuire Damages Report, he uses share of harm attributable to the Marketing Defendants' alleged conduct.[169]

114. Dr. McGuire provides no justification for why (i) he uses the share attributable to all opioid shipments in the McGuire Public Nuisance Report; and (ii) he uses a different set of shares in the McGuire Damages Report.

115. Damages from government costs are included in both reports, and therefore a comparison between the two illustrates the impact of these discrepancies. The comparable government cost damages restricted to 2006-2016 from the McGuire Damages Report is equal to $135 million,[170] which is just below half of the $271 million damages related to the excess public expenditures in the McGuire Public Nuisance Report.

8.2.2. The McGuire Public Nuisance Report suffers from conceptual errors that artificially inflate the damages Dr. McGuire purports to estimate

116. The McGuire Public Nuisance Report suffers from several overarching conceptual errors. First, Dr. McGuire claims to quantify "the net economic burden imposed on the Bellwether communities."[171] However, his approach seems to include costs incurred by entities other than the Bellwether Counties. For example, Dr. McGuire claims damages related to morbidity arising from elevated healthcare costs. His analysis includes patients with private health insurance for whom the costs would be covered by the private insurance company.[172] Dr. McGuire does not explain why costs incurred by entities such as private insurance companies are relevant to alleged damages suffered by the Bellwether Counties.

117. Second, Dr. McGuire performs his analysis to "establish the existence of significant long-term negative effects of shipment on the public health, safety and peace of members of the Bellwether communities."[173] While Dr. McGuire notes that his analysis of harm related to shipments of prescription opioids takes into account any potential economic benefits of the shipments, this is not reflected in his methodology.[174] In particular, although Dr. McGuire identifies and monetizes harm groups that are related to the negative externalities, he does not perform a similar exercise to quantify any benefits arising from opioid medicines such as

[169] McGuire Damages Report, ¶ 11.

[170] McGuire Damages Report, Table IV.14.

[171] McGuire Public Nuisance Report, ¶ 15.

[172] McGuire Public Nuisance Report, ¶ 119 and Appendix H. See Section 8.3.2 for more detailed critiques regarding Dr. McGuire's morbidity analysis.

[173] McGuire Public Nuisance Report, ¶ 42.

[174] McGuire Public Nuisance Report, ¶¶ 23–24.

productivity gains in the labor market.[175] For example, in relation to the effects of shipments on productivity, he simply notes without providing justification, that "the positive and negative short-term effects of shipments approximately cancel out," which he claims to be very conservative.[176]

118. Furthermore, Dr. McGuire not only excludes the offsetting benefits of opioid medicines on those individuals who have been adversely affected by the harms, he also altogether dismisses groups of individuals for whom the benefits from the positive impacts of opioid shipments outweigh any negative effects. For example, Dr. McGuire completely ignores the positive impact of opioid shipments on individuals who followed the prescribed dosage, experienced improved health and did not suffer from OUD.

119. By ignoring the benefits arising from opioid medicines, Dr. McGuire disregards the regulatory context within which opioids are prescribed. In particular, as discussed in Section 5.2.1 above, the FDA has the responsibility to approve drugs and perform risk/benefit assessments,[177] but also has the authority to send additional information to the public, ask manufacturers to amend the labelling, limit the use of the drug, or even withdraw the drug from the market.[178] In addition, the DEA is responsible for the oversight of distribution of opioids[179] and setting quotas.[180]

120. Given that the FDA has not withdrawn Marketing Defendants' opioid products from the market, it is reasonable to infer that in the FDA's view, the benefits of these products outweigh the costs. Such an inference contradicts Dr. McGuire's damages estimates, which imply a large net negative impact over a long horizon. At the very least, the fact that these opioid products, which are subject to stringent regulations and assessment, are currently

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[175] For example, Curie et al. find that opioids may allow some women to work who would otherwise leave the labor force. Janet Curie et al., "U.S. Employment and Opioids: Is There a Connection?" *National Bureau of Economic Research*, 2018, pp. 1–38 at p. 1.

[176] McGuire Public Nuisance Report, ¶ 72.

[177] FDA, "Approved Risk Evaluation and Mitigation Strategies (REMS)," available at https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm, accessed on February 14, 2019.

[178] FDA, "Drug Approval Process," available at https://www.fda.gov/downloads/drugs/resourcesforyou/consumers/ucm284393.pdf, p. 2, accessed on February 22, 2019.

[179] The DEA is responsible for the "[e]nforcement of the provisions of the Controlled Substances Act as they pertain to the manufacture, distribution, and dispensing of legally produced controlled substances." See "Mission," *United States Drug Enforcement Administration*, available at https://www.dea.gov/mission, accessed on May 10, 2019. See Ketcham Report, Section IV.C.

[180] The DEA sets quotas to the manufacturers of controlled substances. Depending on various supply conditions, including status of exports, entry of new manufacturers, or launch of new products, the DEA may revise a company's quota at any time during the year. As an example, a recent proposal by the DEA has been "to reduce more commonly prescribed schedule II opioids, including oxycodone, hydrocodone, oxymorphone, hydromorphone, morphine, and fentanyl." See "Justice Department, DEA propose significant opioid manufacturing reduction in 2019," *United States Drug Enforcement Administration*, August 16, 2018, available at https://www.dea.gov/press-releases/2018/08/16/justice-department-dea-propose-significant-opioid-manufacturing-reduction, accessed on May 9, 2019.

prescribed suggests substantial benefits from these products which Dr. McGuire completely ignores in his damages estimates. Without a proper accounting of the positive benefits, his damages estimates are unreliable.

121. Third, Dr. McGuire's approach assumes that none of the harm would have taken place in the absence of all opioid shipments. In particular, absent all opioid shipments, none of the costs associated with opioid-related mortality, morbidity, crime, child maltreatment and NAS births, would have been incurred. However, this assumption overlooks the fact that at least some of these harms would have occurred absent all opioid shipment. For example,

a. In the context of mortality analysis, Dr. McGuire attributes a share of drug poisoning deaths to all opioid shipments. Among them, some deaths involve both opioids and non-opioids as the underlying drug. Dr. McGuire assumes without basis that those deaths could have been avoided absent all opioid shipments. However, it is conceivable that at least some of those deaths would have occurred due to non-opioid drugs.[181]

b. Similarly, Dr. McGuire improperly assumes that in the absence of OUD, individuals would be free of any substance-abuse issues. As discussed in Section 7.2, this is at odds with the fact that there are several factors unrelated opioid shipments that can trigger substance abuse issues.

122. Finally, Dr. McGuire does not provide any economic justification for why Bellwether Counties would be eligible to claim public nuisance damages for any of the five harm groups. In particular, it is not clear on what grounds the counties would be seeking damages related to harm arising from mortality.

123. To summarize:

a. Dr. McGuire does not explain why costs incurred by entities other than the Bellwether Counties are relevant to alleged damages suffered by the Bellwether Counties;

b. Dr. McGuire's analysis fails to fully account for positive benefits of opioid medicines as suggested in the academic literature, as well as FDA and DEA policy;

c. Dr. McGuire's approach incorrectly assumes none of the harm would have taken place in the absence of all opioid shipments; and

[181] Dr. McGuire's treatment of these mortalities are discussed in more detail below in Section 8.3.1 below.

d. Dr. McGuire does not provide any economic justification for why the Bellwether Counties should claim damages for the negative externalities.

8.2.3. Dr. McGuire commits errors in using share of opioid-related harm estimates

124. In both reports, Dr. McGuire uses Dr. Cutler's share of harm estimates to attribute a fraction of the total opioid-related harm to the Marketing Defendants' alleged conduct. In doing so, Dr. McGuire commits the following conceptual and methodological errors:

a. Dr. McGuire applies Dr. Cutler's share of harm estimates, which are based on mortality rates, to other harm groups and government costs;

b. Dr. McGuire's Public Nuisance Report erroneously uses Dr. Cutler's share of harm attributable to all opioid shipments rather than only the share attributable to the Marketing Defendants' alleged conduct; and

c. Dr. McGuire's estimates rely on Dr. Cutler's share of harm estimates, and therefore any errors in Dr. Cutler's share of harm estimates would affect Dr. McGuire's estimates.

125. First, Dr. McGuire does not perform a separate share of harm analysis for each type of harm. The only share of harm estimate is based on the impact of shipments on mortality rates.[182] Dr. McGuire assumes without basis that any impact shipments have on mortality rates would be equally applicable for other harm groups (e.g., morbidity or crime). Whether the Marketing Defendants' alleged conduct will have the same impact on other harms as on mortality is an empirical question that should be tested, which the Plaintiffs' experts fails to undertake.

126. Second, in the McGuire Public Nuisance Report, Dr. McGuire uses share of harm figures from Appendix III.I of the Cutler Report based on all prescription opioid shipments.[183] In fact, Dr. McGuire notes "I assess the external costs associated with prescription shipments without regard to whether they were due to Defendants' misconduct."[184] However, a few paragraphs later, in the context of mortality calculation, he indicates these shares are "opioid-related deaths *attributable to Defendants' shipments* of

[182] In both reports, Dr. McGuire uses Dr. Cutler's share of harm analyses based on mortality rates. See discussion above in Section 7.6.

[183] McGuire Public Nuisance Report, FN 60.

[184] McGuire Public Nuisance Report, FN 57.

prescription opioids [emphasis in original]."[185] This illustrates an underlying contradiction in Dr. McGuire's approach.

127. Moreover, Dr. Cutler indicates that "the impact of all shipments of prescription opioids, including those not attributable to defendants' misconduct, can be calculated by setting $S_{But-For}$ equal to zero."[186] This assumes an inappropriate counterfactual where there would not be any shipment of prescription opioids absent Marketing Defendants' alleged conduct. This leads to a flawed analysis, which artificially inflates the damages (and substantially so) for three reasons:

a. First, marketing is not the only reason why physicians write prescriptions; there would have been opioid prescriptions written in the absence of marketing.[187]

b. Second, absent Marketing Defendants' alleged conduct, the Marketing Defendants would have continued with their legal promotional efforts, as marketing branded drugs is a common practice within the pharmaceutical industry. This would have resulted in a positive volume of opioid shipments relative to the zero opioid shipments that Dr. McGuire assumes.[188]

c. Third, all prescription opioid shipments include shipments made by non-Defendants, including manufacturers and distributors.[189] This approach holds the Defendants culpable for any harm that may have been caused by the non-Defendants' shipment of prescription opioids. Such an assumption neglects the fact that the non-Defendants would have sold volumes in the but-for world where they would remain unconstrained in their ability to market opioids.

128. Third, as established so far, Dr. McGuire's damages calculations rely on Dr. Cutler's share of harm estimates. Therefore, even ignoring the numerous errors in Dr. McGuire's analyses, any errors in Dr. Cutler's calculations would make Dr. McGuire's analyses unreliable. In Section 7.7, I have discussed several sensitivities to Dr. Cutler's share of harm estimates which illustrate how Dr. Cutler's estimates have been overstated. Exhibit 12 below

[185] McGuire Public Nuisance Report, ¶ 46.

[186] Cutler Report, FN 79.

[187] Dr. Chintagunta cites to numerous academic articles and industry surveys which analyze the impact of pharmaceutical promotion on physicians' prescription decisions. He finds that, while drug promotion can have an effect on physicians' prescribing decisions, their decisions are also dependent on scientific literature, physician and patient characteristics, and many other factors. See Chintagunta Report, Section IX.

[188] Dr. Chintagunta explains that it is common for pharmaceutical companies to promote their products and that Dr. Rosenthal has incorrectly overestimated the excess volume of opioid shipments attributable to the Marketing Defendants' alleged conduct. See Chintagunta Report, Section VI.

[189] Cutler Report, ¶ 83.

shows the impact of these sensitivities on Dr. McGuire's Public Nuisance estimates. It is worth noting that Dr. McGuire's damages estimates are almost halved when using the share of harm attributable to the Marketing Defendants' alleged conduct, instead of share of harm attributable to all opioid shipments. Overall, Exhibit 13 shows that by using flawed inputs from Dr. Cutler's Report, Dr. McGuire inflates his damages estimates considerably. The impact of these sensitivities on Damages estimates in the McGuire Damages Report presented in Section 8.3.6.

EXHIBIT 12
Individual sensitivities for share of harm on Dr. McGuire's Public Nuisance estimates, 2006–2016 (millions)

		Cuyahoga County	Summit County	Total
McGuire Public Nuisance Report estimate		$13,565	$6,492	**$20,056**
Share of harm adjustments[1]				
(A)	Share of harm attributable to Marketing Defendants' alleged conduct	$6,832	$3,306	**$10,138**
(B)	Correct range to which Dr. Rosenthal's shares are applied	$5,765	$2,796	**$8,561**
(C)	Correct range to which Dr. Rosenthal's shares are applied and perform pre-2011 direct approach mortality analysis separately for prescription and illicit opioids	$5,105	$2,513	**$7,618**

Source: McGuire Public Nuisance Report.
Note:
[1] Share of harm sensitivities correspond to columns in Exhibit 8. Sensitivity (A) corresponds to the benchmark estimates Dr. Cutler reports and Dr. McGuire uses in the McGuire Damages Report. Sensitivities (B) and (C) include lagged independent variables in the indirect approach. Section 7.7.2 provides more details about these sensitivities.

8.3. Dr. McGuire overestimates damages related to the five harm groups and government costs

129. In this subsection I present critiques that relate to mortality, morbidity, babies born with NAS, crime, child maltreatment, and government costs. I present a brief description of the methodology Dr. McGuire uses to calculate the opioid-related harm base and focus my critiques on the calculation of the opioid-related harm base.

8.3.1. Dr. McGuire's mortality analysis suffers from conceptual and methodological errors

130. Before applying Dr. Cutler's share of harm, Dr. McGuire first calculates the total amount of opioid-related mortality costs using the following methodology:[190]

Cost of mortality related to opioids
= (Count of deaths related to opioids in county)
× (Value of statistical life adjusted for year and county)

131. In calculating the opioid-related death counts, Dr. McGuire uses the CDC Wonder dataset.[191] Each record in the CDC Wonder mortality data contains two forms of ICD-10 codes: a single code for the "Underlying Cause of Death" and up to 20 additional codes for "Multiple Causes of Death."[192] Dr. McGuire identifies deaths where the underlying cause is drug poisoning and then classifies a death as opioid-related based on the drug involved, as reported in the multiple cause of death field. Namely, he assigns the following ICD-10 codes under the multiple causes of death field to be opioid-related: T40.0 (Opium), T40.1 (Heroin), T40.2 (Other Opioids), T40.3 (Methadone), T40.4 (Other Synthetic Narcotics) and T40.6 (Other and unspecified narcotics).[193] CDC documentation indicates that: "[a]s drug overdose deaths may involve more than one type of drug, some deaths are included in the rates in more than one subcategory. Therefore, categories of drug overdose deaths presented are not mutually exclusive."[194]

132. Dr. McGuire may be overstating opioid-related death counts, because he does not apportion drug poisoning deaths involving both opiates and non-opiates (e.g., opium and cocaine), and rather, attributes all such deaths to opioids alone. For example, he considers all deaths that involved both heroin and cocaine to be opioid-related. This may lead Dr. McGuire to inflate his estimates of the number of opioid-related deaths because in cases where an overdose involved opioids along with other substances, rather than attributing all, he could have apportioned to account for the potential that opioids may not have caused the death.[195]

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[190] McGuire Public Nuisance Report, Appendix C.

[191] McGuire Public Nuisance Report, FN 64 and Appendix C.

[192] Centers for Disease Control and Prevention, "Multiple Cause of Death 1999 – 2017," available at https://wonder.cdc.gov/wonder/help/mcd.html, accessed May 5, 2019.

[193] Plaintiffs' Experts' Data Appendix, pp. 3-5 and McGuire Public Nuisance Report, Appendix C.

[194] Centers for Disease Control and Prevention, "Annual Surveillance Report Of Drug-Related Risks And Outcomes," 2018, p. 39.

[195] *See* Substance Abuse and Mental Health Services Administration, "Using International Classification of Diseases (ICD) Codes to Assess Opioid-Related Overdose Deaths," 2018. "Multiple opioids (for example, heroin and

133. Exhibit 13 and Exhibit 14 below illustrate death counts by year for the underlying drug category in the two counties separately. In each table:

a. The first column illustrates the deaths related to any drug poisoning.

b. The second column shows the count of deaths involving opioids. However, some of these deaths may also involve non-opioids. This is the count used by McGuire.

c. The third column shows the count of deaths involving non-opioids. However, some of these deaths may also involve opioids.

d. The fourth column identifies the death counts that involved both opioid and non-opioid substances.

e. The fifth column shows the proportion of deaths identified by Dr. McGuire to be opioid-related that involved both opioid and non-opioid substances.

134. The exhibit shows that between 2006 and 2016 among all deaths that involve opioids, between 19-33% in Cuyahoga County and 8-26% in Summit County also have non-opiate drugs involved. This has two implications for Dr. McGuire's estimates of opioid-related death counts, neither of which he accounts for:

a. First, given the significant number of deaths that involve both opioids and non-opioids, Dr. McGuire should have adjusted the number of deaths where both opiate and non-opiate substances are involved to appropriately reflect the "true" number of opioid-related deaths, rather than categorizing them all as opioid-related deaths.

b. Second, the difference between the third and the fourth columns show that there are significant numbers of deaths that have only non-opiates as the underlying drugs. As discussed in Section 7.3, there are pre-existing patient conditions that may drive an individual to misuse drugs. It is possible that, absent all opioid shipments, some of the opioid-related deaths may have occurred due to a non-opioid overdose. Furthermore, it is unclear how many

methadone) and/or opioids combined with other drugs (for example, methadone and sleep medications) are often involved in overdose incidences. This can make it difficult to identify specific opioid(s) responsible for overdose(s). In such cases, consider assigning partial attribution to the different opioids involved (for example, overdose incidence where both heroin and methadone are involved can be attributed as 0.5 each). This can prevent overestimating the impact of any particular opioid. When presenting data on such incidences, it is also helpful to provide a footnote that specifies the different opioids and/or other drugs involved."

deaths that involved both opiate and non-opiate drugs would have been avoided in the counterfactual scenario.

135. Therefore, Dr. McGuire commits an error by failing to justify whether it is appropriate to attribute all deaths involving opioid and non-opioid drugs as opioid-related with certainty, thereby overstating opioid-related death counts.

EXHIBIT 13
Opioid-related deaths in Cuyahoga County with both opioid and non-opioid causes

Year	Any narcotic substance identified as a cause of death[1] (A)	Opioid substance identified as a cause of death[2] (B)	Non-opioid substance identified as a cause of death[3] (C)	Opioid and non-opioid substances identified as a cause of death ((B)+(C)-(A))	Proportion of deaths identified as opioid related that also have a non-opioid cause[4] ((B)+(C)-(A))/B
2006	150	104	80	34	32.7%
2007	125	87	65	27	31.0%
2008	143	111	56	24	21.6%
2009	122	92	49	19	20.7%
2010	163	138	51	26	18.8%
2011	205	185	61	41	22.2%
2012	225	191	80	46	24.1%
2013	259	223	85	49	22.0%
2014	261	234	88	61	26.1%
2015	273	245	92	64	26.1%
2016	548	504	202	158	31.3%
Total	**2,474**	**2,114**	**909**	**549**	**26.0%**

Source: CDC Wonder Data; CDC 2018 Annual Surveillance Report of Drug Related Risks and Outcomes; McGuire Public Nuisance Report, Appendix C; Plaintiffs' Experts' Data Appendix
Note:
[1] Each record in the CDC Wonder mortality data contains two forms of ICD-10 codes: a single code for the "Underlying Cause of Death" and up to 20 additional codes for "Multiple Causes of Death." All deaths identified in this table have an underlying cause of death related to overdose. Multiple causes of death that are drug related are identified by the series of T40 ICD-10 codes, along with ICD-10 Code T43.6. The T40 series of ICD codes correspond to poisoning by narcotics and psychodysleptics including opium, heroin and cocaine. T43.6 corresponds to poisoning by psychostimulants with abuse potential.
[2] Figures shown are the opioid-related deaths figures as identified in the McGuire Report. Dr. McGuire classifies a death as opioid-related based on the underlying and multiple causes of death in CDC Wonder Data. Dr. McGuire identifies deaths where the underlying cause of death corresponds to drug poisoning. To identify the multiple causes of death that are opioid-related, he uses the following ICD-10 codes: T40.0 (Opium), T40.1 (Heroin), T40.2 (Other Opioids), T40.3 (Methadone), T40.4 (Other Synthetic Narcotics) and T40.6 (Other and unspecified narcotics). It is possible for a death to have both opioid and non-opioid causes listed on the death certificate.
[3] A death with a non-opioid substance as a cause of death are identified by the following ICD-10 codes: T40.5 (Cocaine), T40.7 (Cannabis (derivatives)), T40.8 (Lysergide (LSD)), T40.9 (Other and unspecified psychodysleptics (hallucinogens)), and T43.6 (psychostimulants with abuse potential).
[4] Represents the percentage of deaths that were identified as having an opioid-related cause in the McGuire Public Nuisance Report, but also have a non-opioid cause.

EXHIBIT 14
Opioid-related deaths in Summit County with both opioid and non-opioid causes

Year	Any narcotic substance identified as a cause of death[1] (A)	Opioid substance identified as a cause of death[2] (B)	Non-opioid substance identified as a cause of death[3] (C)	Opioid and non-opioid substances identified as a cause of death ((B)+(C)-(A))	Proportion of deaths identified as opioid related that also have a non-opioid cause[4] ((B)+(C)-(A))/B
2006	36	25	14	3	12.00%
2007	39	31	14	6	19.35%
2008	28	21	--	--	--
2009	25	23	--	--	--
2010	50	45	12	7	15.56%
2011	38	34	--	--	--
2012	67	60	14	7	11.67%
2013	61	56	14	9	16.07%
2014	111	105	21	15	14.29%
2015	143	135	19	11	8.15%
2016	291	269	92	70	26.02%
Total	**889**	**804**	**200**	**128**	**15.92%**

Source: CDC Wonder Data; CDC 2018 Annual Surveillance Report of Drug Related Risks and Outcomes; McGuire Public Nuisance Report, Appendix C; Plaintiffs' Experts' Data Appendix

Note: [1] Each record in the CDC Wonder mortality data contains two forms of ICD-10 codes: a single code for the "Underlying Cause of Death" and up to 20 additional codes for "Multiple Causes of Death." All deaths identified in this table have an underlying cause of death related to overdose. Multiple causes of death that are drug related are identified by the series of T40 ICD-10 codes, along with ICD-10 Code T43.6. The T40 series of ICD codes correspond to poisoning by narcotics and psychodysleptics including opium, heroin and cocaine. T43.6 corresponds to poisoning by psychostimulants with abuse potential.
[2] Figures shown are the opioid-related deaths figures as identified in the McGuire Report. Dr. McGuire classifies a death as opioid-related based on the underlying and multiple causes of death in CDC Wonder Data. Dr. McGuire identifies deaths where the underlying cause of death corresponds to drug poisoning. To identify the multiple causes of death that are opioid-related, he uses the following ICD-10 codes: T40.0 (Opium), T40.1 (Heroin), T40.2 (Other Opioids), T40.3 (Methadone), T40.4 (Other Synthetic Narcotics) and T40.6 (Other and unspecified narcotics). It is possible for a death to have both opioid and non-opioid causes listed on the death certificate.
[3] A death with a non-opioid substance as a cause of death are identified by the following ICD-10 codes: T40.5 (Cocaine), T40.7 (Cannabis (derivatives)), T40.8 (Lysergide (LSD)), T40.9 (Other and unspecified psychodysleptics (hallucinogens)), and T43.6 (psychostimulants with abuse potential).
[4] Represents the percentage of deaths that were identified as having an opioid-related cause in the McGuire Public Nuisance Report, but also have a non-opioid cause.

136. Dr. McGuire uses VSL as the method of valuation for opioid-related deaths.[196] In doing so, Dr. McGuire commits several errors. First, VSL is not an appropriate metric to calculate the economic harm caused to society due to the death of an individual. Second, there are errors in Dr. McGuire's calculation of the VSL values for the Bellwether Counties. Third, the unreliability of his estimates are illustrated by running a sensitivity on his calculations using an alternative valuation method. I discuss each of these critiques below.

8.3.1.1. VSL is not an appropriate metric to calculate the economic harm caused to society due to the death of an individual

137. The Department of Health Services, which Dr. McGuire cites as justification for using a VSL of $9.3 million, states that "the VSL is not the value of a person's life and should not be

[196] McGuire Public Nuisance Report, Appendix C, p. 1.

described as such. It is the rate at which an individual is willing to trade money for small changes in his or her own mortality risk."[197]

138. The VSL is based on estimates of individuals' willingness to pay (WTP) for reductions in the risk that they face.[198] WTP estimates can be derived from either individuals' stated (in the form of responses to a survey) or revealed preferences (e.g., in the form of consumer's purchase decisions for products that improve their safety).[199] Awarding damages on the basis of VSL can lead to excessive insurance, and therefore would not be an appropriate choice for damages calculation.[200]

139. The CEA (2017) study has used VSL to quantify economic harm due to opioid-related mortality. The study notes that, by using VSL, they "diverge from previous literature."[201] Moreover, the study also acknowledges there were potential biases which implied that VSL estimates were "prone to being overstated", because individuals either "failed to fully understand the nature of the risks they were confronted with", or that "there were often failures to control for confounding factors."[202]

8.3.1.2. There are errors in Dr. McGuire's calculation of the VSL values for the Bellwether Counties

140. Dr. McGuire commits errors in implementing his VSL methodology. He takes a base value of $9.3 million in 2014 dollars as recommended by the U.S. Department of Human and Health Services.[203] In order to adjust this base value for the Bellwether Counties, he accounts for variations across time using price levels and accounts for geographic variations using median income levels as defined in the following equation:[204]

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[197] U.S. Department of Health and Human Services: Office of the Assistant Secretary for Planning and Evaluation, "Guidelines for Regulatory Impact Analysis: A Primer," 2016, p. 5, available at https://aspe.hhs.gov/system/files/pdf/242931/HHS_RIAGuidancePrimer.pdf.

[198] U.S. Department of Health and Human Services: Office of the Assistant Secretary for Planning and Evaluation, "Guidelines for Regulatory Impact Analysis: A Primer," 2016, p. 5, available at https://aspe.hhs.gov/system/files/pdf/242931/HHS_RIAGuidancePrimer.pdf.

[199] W. Kip Viscusi, "The Value of Life in Legal Contexts: Survey and Critique," *American Law and Economics Review*, 2(1), 2000, 195-222 at p. 202, available at https://law.vanderbilt.edu/files/archive/215_Value_of_Life_Legal_Contexts.pdf.

[200] W. Kip Viscusi, "The Value of Life in Legal Contexts: Survey and Critique," American Law and Economics Review, 2000, 195-222 at p. 214, available at https://law.vanderbilt.edu/files/archive/215_Value_of_Life_Legal_Contexts.pdf.

[201] The Council of Economic Advisers, "The Underestimated Cost of the Opioid Crisis," 2017 ("CEA Opioid Study"), p. 3, available at https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The Underestimated Cost of the Opioid Crisis.pdf.

[202] CEA Opioid Study, p. 4.

[203] See McGuire Public Nuisance Report, Appendix C, p. C-2.

[204] McGuire Public Nuisance Report, Appendix C, p. C-3.

$$VSL_{ct} = VSL_{2014} \times \frac{CPI_t}{CPI_{2014}} \times \left(1 + \left[\epsilon \times \frac{(Y_{ct} - Y_{2014})}{(Y_{ct} + Y_{2014})/2}\right]\right)$$

where VSL_{2014} are the VSL values for the US at 2014 base year, CPI (consumer price index) terms adjust the price levels of the year in the numerator with respect to the base year 2014, while the Y terms adjust for the geographic variations by comparing Y_{ct}, i.e., the median income in county c at year t, with Y_{2014}, i.e., the US national median income in 2014.[205]

141. Dr. McGuire's proposed income adjustment is flawed. He has data for the median income of the county, and performs these adjustments at the county level. He inflates the VSL for the mortalities he considers by assuming that those individuals would have on average earned the median income of their respective county, absent OUD. Dr. McGuire cannot reasonably assume that individuals suffering from substance abuse issues would have earned as much as the median individual. For example, NSDUH data analysis shows that individuals with OUD often: (i) abused multiple substances, and (ii) had lower levels of education than those without OUD.[206] As a result, it is likely that individuals who died due to opioid-related causes would have, on average, earned less than the median income of the county even in the absence of all opioid shipments.

142. There are also national studies supporting the claim that lower-income individuals are more likely to be victims of opioid misuse.

a. The U.S. Department of Health and Human Services (the same source that Dr. McGuire uses for his estimates of VSL) said in a 2018 research brief that "[l]ower-income individuals, including those on Medicare and the uninsured are more likely to misuse opioids and have OUD than the general U.S. population."[207]

b. Similarly, the Centers for Disease Control and Prevention argues that "[o]verall, rates of opioid analgesic misuse and overdose death are highest

[205] McGuire Public Nuisance Report, Appendix C, p. C-3.

[206] The NSDUH data on education is provided at a national level and shows that individuals who had shown some dependence on or abuse of opioids in the last year were less likely to be college graduates. See Substance Abuse and Mental Health Data Archive, National Survey on Drug Use and Health: 2-Year RDAS (2016-2017), available at https://rdas.samhsa.gov/#/survey/NSDUH-2016-2017-RD02YR/crosstab/, accessed on May 7, 2019.

[207] See Robin Ghertner and Lincoln Groves, "The Opioid Crisis and Economic Opportunity: Geographic and Economic Trends," U.S. Department of Health and Human Services: Office of the Assistant Secretary for Planning and Evaluation Research Brief, September 2018 ("ASPE Research Brief"), p.1, available at https://aspe.hhs.gov/system/files/pdf/259261/ASPEEconomicOpportunityOpioidCrisis.pdf.

among men, persons aged 20-64, non-Hispanic whites and poor and rural populations."[208]

8.3.1.3. Dr. McGuire's estimates are unreliable

143. Finally, it is worth noting that previous studies that estimate harm caused by opioids have considered lost earnings as a metric to estimate productivity losses. For example, Dr. McGuire cites to a 2017 study by Corwin N. Rhyan.[209] This study estimates lost productivity at $800,000 per person, which is significantly lower than Dr. McGuire's VSL figure, even after his adjustments for CPI and county income levels.[210]

144. Although adopting a methodology based on lost earnings leads to considerably more conservative estimates than a VSL based approach, it could be argued that lost earnings fail to reflect the intangible value of the loss of a life. I believe that it is possible to use alternative metrics to VSL that do account for the intangible value of life, and that still lead to significantly lower estimates of economic harm, illustrating the inappropriateness of VSL as a metric for the purposes of this analysis.

145. In order to demonstrate how Dr. McGuire's unreasonable choice of VSL leads to inflated economic harm figures, I replicate his analysis with an alternative "health capital" approach. Dr. Cutler refers to this methodology in a paper published in 1999, where he defines health capital as the present value of lifetime health.[211] As Dr. Cutler notes in this study, health capital is large relative to the value of income earned during a lifetime, because it is a better measure of the value of life as a whole.[212] Using this approach leads to an estimate of harm that is still significantly lower than the figures Dr. McGuire presents in Table 1 of the Public Nuisance report.

146. I would like to emphasize that I am not suggesting that any economic harm figures presented under this alternative approach reflect the economic harm caused by the

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[208] See Centers for Disease Control and Prevention, "CDC Grand Rounds: Prescription Drug Overdoses – a U.S. Epidemic," Mortality and Morbidity Weekly Report, January 2012, available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm.

[209] McGuire Public Nuisance Report, Table 3.

[210] See Corwin N. Rhyan, "The Potential Societal Benefit of Eliminating Opioid Overdoses, Deaths, and Substance Use Disorders Exceeds $95 Billion Per Year," 2017, *Altarum Research Brief*, ("Rhyan, (2017)") p.2, available at https://altarum.org/sites/default/files/uploaded-publication-files/Research-Brief_Opioid-Epidemic-Economic-Burden.pdf.

[211] See David M. Cutler and Elizabeth Richardson, "Your Money and Your Life: The Value of Health and What Affects It," 1999, *Frontiers in Health Policy Research, Volume 2*, pp.99-132 ("Cutler, (1999)") at p. 107; David M. Cutler and Elizabeth Richardson, "Measuring the Health of the U.S. Population," *Brookings Paper on Economic Activity, Microeconomics*, (1997), pp. 217-282 ("Cutler (1997)") at p. 232.

[212] Cutler (1997) at p.234. Dr. Cutler states that "there is no reason why the value of life as a whole cannot exceed an individual's earning over a lifetime".

Marketing Defendants' alleged conduct. The purpose of presenting economic harm figures estimated through an alternative approach used in the literature is to demonstrate, by means of comparison, the extent to which Dr. McGuire's economic harm figures are unreasonably inflated by his choice of an inappropriate metric like VSL.

147. Dr. Cutler assumes a benchmark value of $100,000 per life year in perfect health.[213] Similar to the VSL, Dr. Cutler's estimate is based on a review of academic studies that calculate the value of a life year based on the willingness to pay for reductions in the risk of injury or death, elicited through either stated or revealed preferences.[214] This approach is thus consistent with the academic literature on VSL.

148. In my sensitivity analysis, I adopt Dr. Cutler's estimate for a year of life in perfect health at $100,000.[215] I then estimate the period over which, in the absence of all opioid shipments, individuals who lost their lives would have accrued additional health capital, henceforth referred to as the "accumulation period."

149. To calculate the value of the accumulation period for individuals in Bellwether Counties, I use CDC national level data which shows the remaining life expectancy of an average American conditional on surviving until 40.[216] I conservatively condition on 40 because the Rhyan (2017) study—also cited by Dr. McGuire in Table 3 of his Public Nuisance Report—estimates the average age of an opioid overdose fatality to be 41 years.[217] The average remaining life expectancy yields an estimate of the accumulation period, assuming that in the absence of all opioid shipments, individuals who died as a result of opioid-related causes would on average have lived the average remaining life expectancy.[218]

150. Having calculated the accumulation period for the Bellwether Counties, I calculate the foregone health capital for each individual, valuing under the assumption of perfect health at

[213] Cutler (1997) at pp. 232-233.

[214] Cutler (1997), p. 232. Measuring the value of life through stated preferences involves directly measuring willingness to pay for reductions in risk through survey questions posed to respondents. Revealed preferences methodologies include looking at labor market data and examining the tradeoff between wages and risk. One could also analyze purchasing decisions in product markets for devices that increase safety, such as smoke detectors and airbags.

[215] Dr. Cutler's base value of a $100,000 is in 1990 dollars. However, he notes that "the literature on the value of life is generally silent about how that value has changed over time". As a result, he assumes the $100,000 value of a life year has not changed over time. See Cutler (1997) at p. 233.

[216] Centers for Disease Control and Prevention, National Vital Statistics Report, United States Life Tables, 2006-2015. Please note that I use the average remaining life expectancy of 2015 to populate the missing value for 2016, as the corresponding life expectancy tables for 2016 have yet to be published.

[217] Rhyan (2017), p. 2. My approach is conservative as remaining life expectancy conditional on being 40 years old is higher than remaining life expectancy conditional on being 41 years old. As a result, this inflates my estimates on the "accumulation period". I take this conservative approach due to data limitation.

[218] I discuss later on in this section how individuals who died of opioid-related causes would on average live for less than the average life expectancy of the county, meaning my estimations of the accumulation period should potentially be lower.

$100,000 per year and discounting future years at a discount rate of 3%. My choice of discount rate is consistent with the academic literature on this subject, including the original study from Dr. Cutler from which I adopt this approach.[219]

151. This yields an estimate of foregone health capital for each individual. To calculate the total foregone health capital for a given year, I multiply this figure with the number of opioid-related deaths for a given year.

152. The reductions in economic harm when compared to Dr. McGuire's VSL methodology can be seen in Exhibit 15. Following Dr. Cutler's health capital methodology yields an economic harm figure that is considerably lower than Dr. McGuire's estimates. The health capital methodology estimates are conservative for the following reasons. First, health capital is calculated on the basis of the value of a life in perfect health. Given the need for prescription opioids, it is reasonable to assume that individuals who died as a result of prescription opioid overdose had pre-existing health conditions and illnesses that reduced their quality of life. Second, my estimates of the accumulation period for both Bellwether Counties are likely inflated, given that the underlying health conditions that necessitated the use of prescription opioids would have on average reduced life expectancy for these individuals, even in the absence of all opioid shipments. Finally, NSDUH data suggests that individuals who have abused or have dependence on opioids are more likely to have lower levels of education. Given that there is a positive correlation between education levels and income,[220] and—as highlighted in a study co-authored by Dr. Cutler—a positive correlation between income and life expectancy,[221] this further supports the conclusion that my estimates of the accumulation period are likely, on average, overstated.

153. In light of the potentially overstated opioid-related mortality counts and the overstated VSL values, Dr. McGuire has overstated the cost of mortality related to opioids. Exhibit 15

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[219] Dr. Cutler uses a discount rate of 3% as his base rate, and presents sensitivities of his results to discount rates of 0% and 6%. See Cutler (1997) at p. 234. See also Curtis S. Florence et al., "The Economic Burden of Prescription Opioid Overdose, Abuse and Dependence in the United States, 2013," *Medical Care*, 54(10), 2016, pp. 901–906 ("Florence (2016)") at p. 902 and Rhyan (2017), p. 4.

[220] George Psacharopoulos and Harry Antony Patrinos, "Returns to Investment in Education: A Decennial Review of the Global Literature," Policy Research Working Paper 8402, World Bank Education Global Practice, April, 2018, available at http://documents.worldbank.org/curated/en/442521523465644318/pdf/WPS8402.pdf, accessed on May 9, 2019. ("This paper reviews and highlights the latest trends and patterns based on a database of 1,120 estimates in 139 countries. The review shows that the private average global rate of return to one extra year of schooling is about 9 percent a year and very stable over decades.")

[221] See Raj Chetty et al., "The Association Between Income and Life Expectancy in the United States, 2001-2014," *JAMA,* 315(16), 2016, pp. 1–4 at p. 1 ("[h]igher income is associated with greater longevity throughout the income distribution…The richest American men live 15 years longer than the poorest men, while the richest American women live 10 years longer than the poorest women. The poorest men in the U.S. have life expectancies comparable to men in Sudan and Pakistan; the richest men in the U.S. live longer than the average man in any country…Longevity [across geographical areas] varies much less across areas for higher-income individuals, who have high life expectancies regardless of where they live.")

below illustrates the impact of each of these sensitivities separately on Dr. McGuire's calculations.

EXHIBIT 15
Sensitivities for mortality, 2006–2016 (millions)

		Cuyahoga County	Summit County	Total
McGuire Public Nuisance Report estimate		$11,279	$5,377	**$16,656**
Adjustment using health capital approach rather than VSL		$3,575	$1,452	**$5,026**
Share of harm adjustments[1]				
(A)	Share of harm attributable to Marketing Defendants' alleged conduct	$5,699	$2,751	**$8,450**
(B)	Correct range to which Dr. Rosenthal's shares are applied	$4,803	$2,327	**$7,130**
(C)	Correct range to which Dr. Rosenthal's shares are applied, and perform pre-2011 direct approach mortality analysis separately for prescription and illicit opioids	$4,273	$2,106	**$6,379**

Source: McGuire Public Nuisance Report; Centers for Disease Control and Prevention, National Vital Statistics Report, United States Life Tables, 2006-2015; Cutler (1997); Rhyan (2017)

Note:
[1] Share of harm sensitivities correspond to columns in Exhibit 8. Sensitivity (A) corresponds to the benchmark estimates Dr. Cutler reports and Dr. McGuire uses in the McGuire Damages Report. Sensitivities (B) and (C) include lagged independent variables in the indirect approach. Section 7.7.2 provides more details about these sensitivities.

8.3.2. Dr. McGuire's morbidity analysis suffers from conceptual and methodological errors

154. Dr. McGuire focuses morbidity calculations on opioid use disorder ("OUD"). The unit for the count analysis is person-years. Before applying Dr. Cutler's share of harm, the total amount of morbidity costs due to opioids are calculated according to the following methodology: [222]

Morbidity related to opioids in person-years =
(adjusted OUD prevalence for counties) × (aged 12+ population in counties)

[222] McGuire Public Nuisance Report, Appendices D and H.

Cost of morbidity related to opioids =
(Morbidity related to opioids in person-years)
× (cost of illness elevated costs from academic studies)

155. Dr. McGuire commits several errors. First, in counting instances of morbidity related to opioids, Dr. McGuire considers both OUD and severe heroin use disorder ("SHUD") patients and apportions a fraction to be attributable to all opioid shipments using Dr. Cutler's share of harm. However, Dr. McGuire's approach does not properly account for whether the apportioned patients would have indeed avoided morbidity in the absence of all opioid shipments. For example, it may be the case some of those apportioned SHUD patients would have consumed illicit opioids and suffered from SHUD in the but-for scenario regardless of all opioid shipments. Therefore, as discussed above in Section 8.2.2, Dr. McGuire potentially overstates the number of person-years suffering from morbidity related to opioids by wrongfully including instances that would not be avoided in the but-for scenario.

156. Second, the cost numbers from the Florence et al. (2016) study overstate costs for OUD patients. In particular, the online appendix to Florence et al. (2016) shows that even before OUD patients were diagnosed with OUD, the average health care costs were on average, higher than those without OUD.[223] The excess costs estimate should account for any pre-existing cost differences, which Florence et al. (2016) do not do. The following values can be deducted from each category: [224]

a. For private health insurance: $180

b. For Medicaid: $3,102.80

c. For Medicare: $1,165.50

157. In light of the potentially overstated count of morbidity and the overstated costs of illness, Dr. McGuire has overstated the cost of morbidity related to opioids. Exhibit 16 below shows sensitivities illustrating the extent to which errors in Dr. McGuire's calculations have overstated the damages related to morbidity.

[223] Florence et al. (2016), online appendix, "Methodological Assumptions," available at http://links.lww.com/MLR/B262, accessed on February 19, 2019, pp 1–23 at pp. 2–7.

[224] Florence et al. (2016), online appendix, "Methodological Assumptions," available at http://links.lww.com/MLR/B262, accessed on February 19, 2019, pp 1–23 at pp. 2–7.

EXHIBIT 16
Sensitivities for morbidity, 2006–2016 (millions)

		Cuyahoga County	Summit County	Total
McGuire Public Nuisance Report estimate		$1,376	$587	**$1,963**
Adjustment correcting for cost of illness		$1,276	$544	**$1,820**
Share of harm adjustments[1]				
(A)	Share of harm attributable to Marketing Defendants' alleged conduct	$681	$290	**$971**
(B)	Correct range to which Dr. Rosenthal's shares are applied	$577	$246	**$823**
(C)	Correct range to which Dr. Rosenthal's shares are applied and perform pre-2011 direct approach mortality analysis separately for prescription and illicit opioids	$498	$212	**$710**

Source: Florence et al. (2016), online appendix, "Methodological Assumptions," available at http://links.lww.com/MLR/B262, accessed on February 19, 2019, pp 1–23 at pp. 2–7.
Note:
[1] Share of harm sensitivities correspond to columns in Exhibit 8. Sensitivity (A) corresponds to the benchmark estimates Dr. Cutler reports and Dr. McGuire uses in the McGuire Damages Report. Sensitivities (B) and (C) include lagged independent variables in the indirect approach. Section 7.7.2 provides more details about these sensitivities.

8.3.3. Dr. McGuire's analysis of harms stemming from babies born with NAS suffers from conceptual and methodological errors

158. Dr. McGuire assumes all instances of babies born with NAS are exclusively due to opioids.[225] Before applying Dr. Cutler's share of harm, the total amount of costs associated with babies born with NAS are calculated according to the following methodology:[226]

$$\text{Cost of NAS births} = (\text{Count of NAS births in county}) \times (\text{excess charge for NAS births}) \times (\text{Ratio of net hospital revenues to gross hospital charges})$$

159. Dr. McGuire calculates the excess charges for NAS births as the difference between the average charge for NAS births and the average charge for all births, across all Ohio hospitals.[227] In doing so, Dr. McGuire assumes, without any factual evidence, that absent all opioid shipments, on average newborns would have had the same health conditions as an

[225] McGuire Public Nuisance Report, ¶ 53.
[226] McGuire Public Nuisance Report, Table E.1.
[227] McGuire Public Nuisance Report, Table E.3.

average birth. However, given that opioid abuse is correlated with other substance abuse, even absent all opioid shipments, the impacted mothers would have a higher propensity to abuse other substances, potentially resulting in births with other complications that incur higher costs than the average birth.[228]

160. Additionally, Dr. McGuire applies the ratio of net revenues to gross hospital charges across all hospital procedures to the excess charges to derive the excess costs associated with a NAS birth.[229] Dr. McGuire does not provide a justification for why this ratio would be consistent across all hospital procedures, nor does he provide evidence that applying this ratio to estimate excess NAS costs would not lead to inflated estimates.

161. In light of the potentially overstated excess hospital charges, Dr. McGuire likely overstated the cost of NAS births related to opioids. The sensitivity below illustrates errors in Dr. McGuire's calculations.

EXHIBIT 17
Sensitivities for NAS births, 2006–2016 (millions)

		Cuyahoga County	Summit County	Total
McGuire Public Nuisance Report estimate		$9.4	$6.6	**$16.1**
Share of harm adjustments[1]				
(A)	Share of harm attributable to Marketing Defendants' alleged conduct	$4.7	$3.3	**$8.1**
(B)	Correct range to which Dr. Rosenthal's shares are applied	$3.9	$2.8	**$6.7**
(C)	Correct range to which Dr. Rosenthal's shares are applied and perform pre-2011 direct approach mortality analysis separately for prescription and illicit opioids	$3.4	$2.4	**$5.9**

Source: McGuire Public Nuisance Report.

Note:
[1] Share of harm sensitivities correspond to columns in Exhibit 8. Sensitivity (A) corresponds to the benchmark estimates Dr. Cutler reports and Dr. McGuire uses in the McGuire Damages Report. Sensitivities (B) and (C) include lagged independent variables in the indirect approach. Section 7.7.2 provides more details about these sensitivities.

[228] See ¶ 141 above for a discussion of the correlation between opioid abuse and other substance abuse based on NSDUH data. See also Section 7.3 for a discussion about pre-existing conditions that increase the likelihood of drug misuse.

[229] McGuire Public Nuisance Report, Table E.3.

8.3.4. Dr. McGuire's crime analysis suffers from conceptual and methodological errors

162. Dr. McGuire's crime cost calculations focus on 18 broad categories of crimes, including Aggravated Assault, Forgery and Fraud, and Robbery.[230] Before applying Dr. Cutler's share of harm, Dr. McGuire calculates the total amount of crime costs due to opioids for each crime category according to the following methodology:[231]

$$\begin{aligned}\text{Crimes related to opioids}[232] = &\ (\text{number of offenses in county}) \\ &\times (\text{percent of crime that is drug related for each offense}) \\ &\times (\text{share of opioid-related substance disorders})\end{aligned}$$

$$\begin{aligned}\text{Cost of crimes related to opioids} = &\ (\text{Crimes related to opioids}) \\ &\times (\text{Cost of crime from academic studies})\end{aligned}$$

163. Dr. McGuire uses a mapping to allocate crime counts from National Incident-Based Reporting System ("NIBRS") into the eighteen broad crime categories. He obtains twelve of his eighteen crime offense categorizations from McCollister et al. (2010) and the other six offense categorizations from Miller and Bhattacharya (2013).[233] Dr. McGuire then groups the costs associated with each offence into the following groups; (i) Direct Costs, which consists of Crime Victim Cost; (ii) Implicit Costs, which consists of Crime Career Costs; and (iii) Intangible Costs, which consists of Pain and Suffering, and Adjusted Risk of Homicide.[234]

164. NIBRS data is based on incidents and arrests for crime, and not based on convictions.[235] The dataset thus could include individuals who were arrested but either had their charges dropped, or were ultimately acquitted, both of which would inflate Dr. McGuire's estimates of economic harm due to excess crime.

165. Additionally, Dr. McGuire mistakenly classifies eight instances of "Justifiable Homicide" as murder for Cuyahoga County (the NIBRS database states that Justifiable Homicide is "not a crime").

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[230] McGuire Public Nuisance Report, Appendix F.

[231] McGuire Public Nuisance Report, Appendix F.

[232] The exception to this calculation is the category of "Drug Crimes", where Dr. McGuire uses the percentage of drug seizures in Ohio that contained opioids to estimate the number of drug crimes that are opioid-related. See McGuire Public Nuisance Report, Appendix F.

[233] McGuire Public Nuisance Report, Appendix F, p. F-8.

[234] McGuire Public Nuisance Report Table F.3.

[235] United States Department of Justice, and Federal Bureau of Investigation, "National Incident-Based Reporting System Volume 1: Data Collection Guidelines," August 2010, p. 39.

166. Dr. McGuire's methodology for valuation of crimes considers a total of 18 crime categories, twelve of which come from one study and the remaining six come from another. Although these studies have crime costs reported in different base years, Dr. McGuire fails to align them.[236]

167. Dr. McGuire uses different estimates of VSL in his calculations for mortality and crime. VSL is used to value the economic harm due to an opioid overdose death in his mortality section, and intangible costs for crime categories obtained from McCollister et al. (2010).[237] As discussed in Section 8.3.1 above, Dr. McGuire uses a base VSL of $9.3 million in 2014 dollars for the mortality calculations, while the intangible costs are based on a VSL of $8.4 million in 2008 dollars.[238]

168. In light of the overstated crime counts and the errors in calculating the cost of crime, Dr. McGuire has overstated the cost of crime related to opioids. These sensitivities illustrate the errors in Dr. McGuire's calculations.

[236] The McCollister et al. (2010) study uses crime costs reported in 2008 dollars, while the Miller and Bhattacharya (2013) study uses crime costs reported in 2010 dollars. Dr. McGuire fails to adjust for these discrepancies in his calculations.

[237] McGuire Public Nuisance Report Table F.3.

[238] McGuire Public Nuisance Report, Table F. 3; McGuire Public Nuisance Report Appendix C, p. 2. See also Kathryn E. McCollister et al., "The cost of crime to society: New Crime-Specific Estimates for Policy and Program Evaluation," *Drug and Alcohol Dependence*, 108(1), 2010, pp. 98–109.

EXHIBIT 18
Sensitivities for crime, 2006–2016 (millions)

		Cuyahoga County	Summit County	Total
McGuire Public Nuisance Report estimate		$327	$126	**$453**
Adjustment where justified homicide is not categorized as a crime		$326	$126	**$452**
Share of harm adjustments[1]				
(A)	Share of harm attributable to Marketing Defendants' alleged conduct	$161	$62	**$223**
(B)	Correct range to which Dr. Rosenthal's shares are applied	$138	$53	**$191**
(C)	Correct range to which Dr. Rosenthal's shares are applied and perform pre-2011 direct approach mortality analysis separately for prescription and illicit opioids	$119	$46	**$164**

Source: McGuire Public Nuisance Report, Appendix F.

Note:
[1] Share of harm sensitivities correspond to columns in Exhibit 8. Sensitivity (A) corresponds to the benchmark estimates Dr. Cutler reports and Dr. McGuire uses in the McGuire Damages Report. Sensitivities (B) and (C) include lagged independent variables in the indirect approach. Section 7.7.2 provides more details about these sensitivities.

8.3.5. Dr. McGuire's child maltreatment analysis suffers from conceptual and methodological errors

169. Dr. McGuire focuses on two possible sources of damages related to child maltreatment: lost productivity and additional special education costs.[239] Before applying Dr. Cutler's share of harm, the total child maltreatment costs related to opioids are calculated according to the following methodology:[240]

Cost of maltreatment cases related to opioids = (Maltreatment cases in the counties)
× (productivity losses + expected additional special education costs)

170. Regarding counts of child maltreatment, Dr. McGuire adopts findings from Dr. Young's report.[241]

[239] McGuire Public Nuisance Report, ¶ 130.
[240] McGuire Public Nuisance Report, Appendix G.
[241] McGuire Public Nuisance Report, Appendix G.

171. Dr. McGuire relies on academic studies for his valuation methodology.[242] The productivity losses are estimated to be $6,500 per year per maltreated child,[243] and is based on a national study of a sample of maltreated children from late 1960's to early 1970's. The sample comprises "court substantiated cases of childhood physical and sexual abuse,"[244] which, as the authors themselves acknowledge, is likely more severe than unreported cases of abuse or neglect.[245] Therefore, taking into account less severe unreported cases, the true mean of lost productivity per maltreated child would likely be lower than what was reported in the study.

172. In light of the potentially overstated child maltreatment counts and the potentially overstated cost of illness, Dr. McGuire may have overstated the cost of child maltreatment related to opioids. These sensitivities illustrate the errors in Dr. McGuire's calculations.

EXHIBIT 19
Sensitivities for child maltreatment, 2006–2016 (millions)

		Cuyahoga County	Summit County	Total
McGuire Public Nuisance Report estimate		$401	$297	**$698**
Share of harm adjustments[1]				
(A)	Share of harm attributable to Marketing Defendants' alleged conduct	$201	$149	**$350**
(B)	Correct range to which Dr. Rosenthal's shares are applied	$170	$126	**$295**
(C)	Correct range to which Dr. Rosenthal's shares are applied and perform pre-2011 direct approach mortality analysis separately for prescription and illicit opioids	$149	$110	**$259**

Source: McGuire Public Nuisance Report, Appendix G.

Note:
[1] Share of harm sensitivities correspond to columns in Exhibit 8. Sensitivity (A) corresponds to the benchmark estimates Dr. Cutler reports and Dr. McGuire uses in the McGuire Damages Report. Sensitivities (B) and (C) include lagged independent variables in the indirect approach. Section 7.7.2 provides more details about these sensitivities.

[242] McGuire Public Nuisance Report, Appendix G.

[243] Janet Currie and Cathy S. Widom, "Long-Term Consequences of Child Abuse and Neglect on Adult Economic Well-Being," *Child Maltreatment*, 15(2), 2010, pp. 111–120 at p. 115 ("Currie and Widom (2010)").

[244] Currie and Widom (2010), p. 112.

[245] Currie and Widom (2010), p. 118.

8.3.6. Dr. McGuire's government costs are overstated due to conceptual and methodological errors in both reports

173. Dr. McGuire identifies nine divisions in Cuyahoga and ten divisions in Summit County that were affected by the opioid abuse crisis.[246] Before applying Dr. Cutler's share of harm, Dr. McGuire calculates the total amount of government costs related to opioids for each division:[247]

Total affected cost base to tackle the opioid abuse crisis =
[(Total compensation costs) × (Adjustment Factors)] +
(Total non-compensation costs)

Government costs related to opioids =
(Total affected cost base to tackle the opioid abuse crisis)
× (Share of activities that are opioid-related)

174. Dr. McGuire relies on interviews to identify the affected government departments.[248] Similarly, these interviews inform the identification of the varying costs, which he refers to as the Compensation Costs,[249] and the non-varying costs, which he refers to as the Non-Compensation Costs.[250] However, he does not provide a full back up from the interviews, such as detailed meeting notes that could be used to determine the cost categorizations. In fact Dr. McGuire admits not attending any meetings nor taking meeting notes.[251] Therefore, I have no means to verify the accuracy of his cost assessments.

175. Dr. McGuire adjusts compensation costs by an overhead adjustment factor in order to exclude costs of staff "that were unlikely to have been affected by the crisis."[252] He makes a similar adjustment to the crime and public safety divisions in order to exclude non-crime related activities out of the affected cost base.[253] However, he does not make any such adjustment for non-compensation costs. The funds spent on non-compensation costs could be spent on administrative tasks that are not affected by the opioid abuse crisis, and therefore would have to be adjusted under Dr. McGuire's methodology.

[246] McGuire Damages Report, ¶¶ 52, 54.
[247] McGuire Damages Report, Appendices IV.C-D.
[248] McGuire Damages Report, ¶ 9.
[249] McGuire Damages Report, ¶¶ 59–60.
[250] McGuire Damages Report, ¶ 61.
[251] Deposition of Thomas McGuire, April 23, 2019 ("McGuire Deposition"), pp. 72:18–86:1.
[252] McGuire Damages Report, ¶ 60.
[253] McGuire Damages Report, ¶ 74.

176. As discussed above in Section 8.3.4, Dr. McGuire identifies 18 categories of crime in his damages assessment. Of these 18 categories, six come from the paper Miller and Bhattacharya (2013). For these six categories, Dr. McGuire includes "Public Services" costs in his damages calculations, which includes "police, fire, EMS, [and] victim services."[254] This suggests there is likely double counting with government costs related to public safety divisions (e.g., the Sheriff's department).

177. In applying Dr. Cutler's opioid-related share of harm figures, Dr. McGuire may be overstating opioid-related costs if either of the following holds:

a. The department provides multiple services and the activity on which the opioid-related percentage metric is measured is disproportionately higher than the share of opioid-related tasks in other activities.

b. If the opioid-related activities on average are cheaper to offer than non-opioid-related activities, then the opioid-related affected cost base would potentially include non-opioid-related costs.

178. For instance, consider the Cuyahoga Division of Children and Family Services (DCFS). Dr. McGuire applies Dr. Cutler's "Opioid-related % of Removals" figure to the total affected costs. This figure is calculated using the "percentage of children taken into custody in 2015 in Summit and Cuyahoga counties that had parents who were using opioids at the time of removal."[255] Dr. Cutler then applies this figure across all relevant years "under the assumption that opioid-related child removals track the trend in the annual changes of OUD treatment expenses in the counties."[256]

179. Dr. McGuire applies this percentage to the total affected costs for the Cuyahoga County Division of Children and Family.[257] However, in doing so, he might overstate damages because he is assuming a cost-base that is too wide for this particular adjustment.

a. Dr. Cutler's Opioid-related % of Removals might be applicable only to services provided that relate specifically to removals. Both Cuyahoga County and Summit County's Child Services divisions offer services beyond foster care. For example, Cuyahoga County offers a program titled "family

[254] T. Miller, and S. Bhattacharya, "Incidence and Cost of Carbon Monoxide Poisoning for All Ages, Pool and Spa Submersions for Ages 0– 14, and Lead Poisoning for Ages 0-4," March 29, 2013, Table 20, available at https://www.cpsc.gov/s3fs-public/pdfs/IncidenceandCostofCarbonMonoxidePoisoningPoolandSpaSubmersionandLeadPosioning_0.pdf, accessed on May 10, 2019.

[255] Cutler Report, ¶ 44.

[256] Cutler Report, ¶ 44.

[257] McGuire Damages Report, Appendix IV.C-2.1.

preservation / reunification services", while Summit County offers a program called "independent living grant."[258] It is likely the case that costs related to these programs are not directly related to child removals. Therefore, Dr. McGuire is incorrectly applying a share of opioid-related removals to costs that are not related to removals.

b. Instead, Dr. McGuire should have repeated Dr. Cutler's exercise for each potential category of costs within this department. For example, he should have applied the share of removals only to categories that are directly related to removals (such as foster care), and separately calculated and applied an "opioid-related" percentage to services that are not related to removals (such as support for independent living programs).

180. If it is the case that other categories of services provided by these divisions have a smaller percentage of costs related to opioids (for instance, if the percent due to removals is 10% and the percent of family programming that now focuses on coping with an opioid-addicted family member is 2%), then Dr. McGuire's damages figures are likely inflated.

181. Additionally, Dr. McGuire applies an opioid-related percentage amount to the total affected costs for all Bellwether Government divisions that are likely to have been impacted by the crisis.[259] In doing this, Dr. McGuire often assumes that these opioid-related adjustments are proportionate to the costs. For example, Dr. McGuire applies Dr. Cutler's Opioid-Related % of Prisoners figure to total affected costs for Summit County Jail as part of his damages calculation. In order to calculate the Opioid-Related % of Prisoners figure, Dr. Cutler takes the annual data on the number of state prisoners with a sentence of more than one year. He first takes the proportion of drug-related prisoners, and then uses the ratio of opioid use disorder to substance use disorder to apportion the number of opioid-related prisoners.[260] Dr. McGuire uses this volume-based percentage to apportion costs.[261]

182. In applying this figure to the Summit County Jail affected costs amount, Dr. McGuire is assuming that costs could be apportioned using the share of opioid-related prisoners, which suggests he implicitly assumes that the costs between opioid-related and other prisoners are the same on average. However, Dr. McGuire offers no evidence that the costs would be the same across offense types and therefore calculates unreliable estimates of the affected costs.

[258] McGuire Damages Report, Appendix IV.C-2.2, Appendix IV.D-2.2.
[259] McGuire Damages Report, Table IV.9–10.
[260] Cutler Report, Appendices III.C.2–3.
[261] McGuire Damages Report, Appendix IV.C.-8.1; McGuire Damages Report, Appendix IV.D-7.1.

183. In fact, a paper by Hunt et al. (2016) confirms that calculating the costs of opioid-related crimes using proportion of crimes could inflate the cost of opioid-related crimes.[262] The authors list many of their results surrounding the wide variation in the costs of crime by type of crime in the abstract of the paper: "[T]his study finds the national average costs to taxpayers for judicial/legal services per reported crime are likely around the following (in 2010 dollars): $22,000–$44,000 (homicide), $2000–$5000 (rape and sexual assault), $600–$1300 (robbery), $800–$2100 (aggravated assault), $200–$600 (burglary), $300–$600 (larceny/theft), and $200–$400 (motor vehicle theft)."[263] While not mentioning drug related crimes directly, this points to a wide variation in the cost of investigating crimes. By accounting for the proportional cost of crime using counts, expensive murder investigations are assigned too low of a cost. This leads to a disproportionate representation of the true cost of crime, potentially inflating costs of public services related to opioid-related crimes.

184. In light of the overstated total affected cost base and the erroneous application of opioid-related share of harm, Dr. McGuire overstates government costs incurred due to opioids. These sensitivities illustrate the errors in Dr. McGuire's calculations.

[262] See, Priscilla Hunt, James Anderson, Jessica Saunders, "The Price of Justice: New National and State-Level Estimates of the Judicial and Legal Costs of Crime to Taxpayers", American Journal of Criminal Justice, 42(2), 2016, pp. 231–254 ("Hunt et al. (2016)") at p. 231.

[263] See, Hunt et al. (2016) at p. 231.

EXHIBIT 20
Sensitivities for government costs in McGuire Public Nuisance Report, 2006–2016 (millions)

	Cuyahoga County	Summit County	Total
McGuire Public Nuisance Report estimate	$172	$99	**$271**
Adjustment of non-compensation costs	$166	$94	**$259**
Share of harm adjustments[1]			
(A) Share of harm attributable to Marketing Defendants' alleged conduct	$86	$50	**$135**
(B) Correct range to which Dr. Rosenthal's shares are applied	$73	$41	**$114**
(C) Correct range to which Dr. Rosenthal's shares are applied, and perform pre-2011 direct approach mortality analysis separately for prescription and illicit opioids	$63	$36	**$100**

Source: McGuire Public Nuisance Report.

Note:
[1] Share of harm sensitivities correspond to columns in Exhibit 8. Sensitivity (A) corresponds to the benchmark estimates Dr. Cutler reports and Dr. McGuire uses in the McGuire Damages Report. Sensitivities (B) and (C) include lagged independent variables in the indirect approach. Section 7.7.2 provides more details about these sensitivities.

EXHIBIT 21
Sensitivities for government costs in McGuire Damages Report, 2006–2016 (millions)

	Cuyahoga County	Summit County	Total
McGuire Damages Report estimate	$126	$69	**$194**
Adjustment of non-compensation costs	$121	$65	**$186**
Share of harm adjustments[1]			
(B) Correct range to which Dr. Rosenthal's shares are applied	$108	$58	**$166**
(C) Correct range to which Dr. Rosenthal's shares are applied, and perform pre-2011 direct approach mortality analysis separately for prescription and illicit opioids	$96	$52	**$149**

Source: McGuire Damages Report

Note:
[1] Share of harm sensitivities correspond to columns in Exhibit 8. Sensitivities (B) and (C) include lagged independent variables in the indirect approach. Section 7.7.2 provides more details about these sensitivities.

8.4. Dr. McGuire's damages calculations in both reports are overstated

185. In this subsection, I summarize the sensitivities presented in the previous subsection for individual harm groups. I present the stacked impact of the sensitivities and compare against Dr. McGuire's calculations separately for the McGuire Public Nuisance Report and the McGuire Damages Report. Please note that the figures only illustrate a lower bound of the extent to which Dr. McGuire overstates alleged damages, as there have been several errors that have not been quantified.

186. Exhibit 22 and Exhibit 23 illustrate the combined sensitivities for the Bellwether Counties separately.

EXHIBIT 22
Combined sensitivities for all harms in McGuire Public Nuisance Report, Cuyahoga County 2006–2016 (millions)

		Mortality	Morbidity	NAS	Crime	Child Maltreatment	Government Costs	Total
McGuire Public Nuisance Report estimate		$11,279	$1,376	$9	$327	$401	$172	**$13,565**
Adjust for all sensitivities[1]								
(A)	Share of harm attributable to Marketing Defendants' alleged conduct	$1,799	$631	$5	$161	$201	$82	**$2,878**
(B)	Correct range to which Dr. Rosenthal's shares are applied	$1,518	$535	$4	$138	$170	$70	**$2,434**
(C)	Correct range to which Dr. Rosenthal's shares are applied and perform pre-2011 direct approach mortality analysis separately for prescription and illicit opioids	$1,342	$461	$3	$118	$149	$61	**$2,135**

Source: McGuire Public Nuisance Report; Centers for Disease Control and Prevention, National Vital Statistics Report, United States Life Tables, 2006-2015; Cutler (1997); Rhyan (2017); Florence et al. (2016).

Note:
[1] Share of harm sensitivities correspond to columns in Exhibit 8. Sensitivity (A) corresponds to the benchmark estimates Dr. Cutler reports and Dr. McGuire uses in the McGuire Damages Report. Sensitivities (B) and (C) include lagged independent variables in the indirect approach. Section 7.7.2 provides more details about these sensitivities.

EXHIBIT 23
Combined sensitivities for all harms in McGuire Public Nuisance Report, Summit County 2006–2016 (millions)

		Mortality	Morbidity	NAS	Crime	Child Maltreatment	Government Costs	Total
McGuire Public Nuisance Report estimate		$5.377	$587	$7	$126	$297	$99	**$6,492**
Adjust for all sensitivities[1]								
(A)	Share of harm attributable to Marketing Defendants' alleged conduct	$740	$269	$3	$62	$149	$47	**$1,271**
(B)	Correct range to which Dr. Rosenthal's shares are applied	$627	$228	$3	$53	$126	$39	**$1,076**
(C)	Correct range to which Dr. Rosenthal's shares are applied and perform pre-2011 direct approach mortality analysis separately for prescription and illicit opioids	$565	$197	$2	$46	$110	$34	**$954**

Source: McGuire Public Nuisance Report; Centers for Disease Control and Prevention, National Vital Statistics Report, United States Life Tables, 2006-2015; Cutler (1997); Rhyan (2017); Florence et al. (2016).

Note:
[1] Share of harm sensitivities correspond to columns in Exhibit 8. Sensitivity (A) corresponds to the benchmark estimates Dr. Cutler reports and Dr. McGuire uses in the McGuire Damages Report. Sensitivities (B) and (C) include lagged independent variables in the indirect approach. Section 7.7.2 provides more details about these sensitivities.

187. Exhibit 24 presents the combined sensitivities for the two Bellwether Counties. As can be seen below, Dr. McGuire's total damages estimates are overstated at the very least by about 80%.

EXHIBIT 24
Combined sensitivities for all harms in McGuire Public Nuisance Report, Bellwether Counties 2006–2016 (millions)

		Mortality	Morbidity	NAS	Crime	Child Maltreatment	Government Costs	Total
McGuire Public Nuisance Report estimate		$16,656	$1,963	$16	$453	$698	$271	**$20,056**
Adjust for all sensitivities[1]								
(A)	Share of harm attributable to Marketing Defendants' alleged conduct	$2,539	$900	$8	$223	$350	$129	**$4,149**
(B)	Correct range to which Dr. Rosenthal's shares are applied	$2,145	$763	$7	$191	$295	$109	**$3,510**
(C)	Correct range to which Dr. Rosenthal's shares are applied and perform pre-2011 direct approach mortality analysis separately for prescription and illicit opioids	$1,907	$658	$6	$164	$259	$95	**$3,090**

Source: McGuire Public Nuisance Report; Centers for Disease Control and Prevention, National Vital Statistics Report, United States Life Tables, 2006-2015; Cutler (1997); Rhyan (2017); Florence et al. (2016).

Note:
[1] Share of harm sensitivities correspond to columns in Exhibit 8. Sensitivity (A) corresponds to the benchmark estimates Dr. Cutler reports and Dr. McGuire uses in the McGuire Damages Report. Sensitivities (B) and (C) include lagged independent variables in the indirect approach. Section 7.7.2 provides more details about these sensitivities.

188. Exhibit 25 presents the combined sensitivities for the McGuire Damages Report calculations.

EXHIBIT 25
Combined sensitivities for McGuire Damages Report, 2006–2018 (millions)

		Cuyahoga County	Summit County	Total
McGuire Public Nuisance Report estimate		$126	$69	**$194**
Adjust for all sensitivities[1]				
(B)	Correct range to which Dr. Rosenthal's shares are applied	$104	$55	**$159**
(C)	Correct range to which Dr. Rosenthal's shares are applied and perform pre-2011 direct approach mortality analysis separately for prescription and illicit opioids	$93	$50	**$142**

Source: McGuire Damages Report; Centers for Disease Control and Prevention, National Vital Statistics Report, United States Life Tables, 2006-2015; Cutler (1997); Rhyan (2017); Florence et al. (2016).

Note:
[1] Share of harm sensitivities correspond to columns in Exhibit 8. Sensitivities (B) and (C) include lagged independent variables in the indirect approach. Section 7.7.2 provides more details about these sensitivities.

8.5. Dr. McGuire's damages figures are uninformative

189. The Plaintiffs allege that the Defendants were responsible for the alleged opioid-related harms. However, Dr. McGuire does not apportion his estimated figures between the Defendants. Therefore, in addition to the conceptual and methodological errors discussed in the previous sections, it is unclear how informative Dr. McGuire's estimates are.

190. In his deposition, Dr. McGuire also acknowledges he has not undertaken the analysis to apportion damages attributable to any actor. Namely, he has not "decided what portion of these might be attributable to some other actors or who might be jointly responsible for something."[264] Dr. McGuire further confirmed that he "[has not] done that analysis."[265]

[264] McGuire Deposition, pp. 193:3–193:6.

[265] McGuire Deposition, p. 193:6.

9. DR. MCCANN'S EXPERT REPORTS CONTAIN SERIOUS CONCEPTUAL AND METHODOLOGICAL ERRORS AND ARE UNINFORMATIVE WITH RESPECT TO MONITORING SUSPECT ORDERS BY MANUFACTURERS

191. Dr. McCann has submitted three expert reports.[266] In the McCann Initial Report, he documents how he processed, validated and augmented opioid transaction data produced by the DEA and the Defendants.[267] He also summarizes shipments in the Automation of Reports and Consolidated Orders System (ARCOS) electronic data from the DEA, especially those shipments into Bellwether Counties. His Initial Report identifies transactions from distributors to dispensers over the 1997–2018 period for Bellwether Counties in Ohio. He compares ARCOS DEA data with ARCOS Retail Drug Summary Reports and data from Defendants, and concludes that the ARCOS DEA 2006–2014 data set is reliable because it closely matches the DEA's Retail Drug Summary Reports for January 2006 through December 2014.[268]

192. In the McCann Supplemental Report, Dr. McCann supplements the ARCOS data with "chargeback" data and IQVIA/IMS data. In his Supplemental Report he documents how he further processes and validates opioid transaction data produced by the DEA to attribute distributors-to-dispensers transactions to the Marketing Defendants in the Bellwether Counties.[269]

193. Dr. McCann's Initial Report applies five different threshold measures and assumptions to "flag" transactions from distributors to dispensers over the 1997–2018 time period. Dr. McCann does not explicitly state the purpose of his threshold filter analysis, other than to say that he was asked to apply "certain algorithms to the ARCOS Data."[270] Dr. McCann later indicates that Distributor Defendants had an "obligation to detect and investigate" these flagged transactions.[271] For the purposes of this report I assume that Dr. McCann's threshold filters were designed to detect allegedly suspicious transactions, and use this terminology throughout the remainder of this section.

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[266] The three reports Dr. McCann submitted are Dr. McCann's Initial Report, First Supplemental Report and Second Supplemental Report. Dr. McCann's First Supplemental Report inserted some Figures and Tables which were inadvertently excluded from his Initial Report. My analysis and opinions are based on his Initial Report and his Second Supplemental Report, which I will refer to as "Supplemental Report".

[267] Dr. McCann refers to "Distributor Defendants" and "Manufacturing Defendants" collectively as "Defendants." For the sake of consistency with the present report, I will refer to Manufacturing Defendants as "Marketing Defendants."

[268] McCann Initial Report, ¶ 14.

[269] McCann Supplemental Report, ¶¶ 5-6.

[270] McCann Initial Report, ¶ 12. McCann Supplemental Report, ¶ 7.

[271] McCann Initial Report, ¶ 132.

194. In his Supplemental Report, Dr. McCann applies the same filters and assumptions to transactions with dispensers that he has attributed to Marketing Defendants over the 2006-2014 time period.

195. In the remainder of this section, I first provide, in Subsection 9.1, an overview of how Dr. McCann validates and augments the ARCOS transaction data, and how Dr. McCann attributes transactions with dispensers back to Marketing Defendants. In Subsection 9.2, I discuss the threshold filters he applies to identify flagged transactions. Then in Subsection 9.3, I discuss the conceptual flaws and methodological errors in Dr. McCann's approach, which render his analyses unreliable and uninformative. In Subsection 9.4, I consider the pharmaceutical supply chain and discuss how Marketing Defendants are unlikely to be able to identify suspicious transactions based on chargeback and IQVIA/IMS data.

9.1. Summary of Dr. McCann's augmentation and validation of transaction data

196. Dr. McCann's analysis relies primarily on the DEA's ARCOS dataset, augmented and validated using a number of other datasets, as described below. The ARCOS dataset aggregates the transactions reported to the DEA by manufacturers and distributors.[272] The ARCOS data includes buyer and seller identification numbers and transaction information, including NDC drug code and quantity.

197. Dr. McCann states that he removes various types of transactions from the ARCOS data before conducting his analysis, including: duplicate transactions; transactions where the drug is not one of the 14 opioids considered in his analysis; transactions between reverse distributors, analytical labs, imports/exports, and researchers; transactions lost in transit; and transactions indicated as erroneous or with "obvious errors."[273] Exhibit 26, below, reports the number of transactions and dosage units that are removed due to Dr. McCann's correction. Exhibit 26 is limited to transactions between manufacturers, distributors, and dispensers. While these corrections only remove 3.3% of transactions between manufacturers, distributors and dispensers; they account for 41.2% of dosage units. While these exclusions from the ARCOS data set may be valid, they also disproportionately remove transactions representing large shipments of opioids.

[272] McCann Initial Report, ¶ 23. The ARCOS data covers all 50 states, the District of Columbia, Puerto Rico, Guam, U.S. Virgin Islands, American Samoa, and Northern Mariana Islands, Armed Forces (Americas, EMEA and Pacific), and Palau.

[273] McCann Initial Report, ¶ 55.

EXHIBIT 26
Count of transactions in the ARCOS data, with and without Dr. McCann's corrections

		Transactions			Dosage Units		
		ARCOS transactions	Dr. McCann's corrected ARCOS transactions	Percent difference	ARCOS transactions	Dr. McCann's corrected ARCOS transactions	Percent difference
	Shipments to Dispensers						
1.	from Manufacturers	2,762,706	2,756,758	0.2%	1,963,746,971	1,955,595,851	0.4%
2.	from Distributors	422,984,879	422,339,037	0.2%	134,013,039,950	133,869,556,048	0.1%
	Shipments to Distributors						
3.	from Manufacturers	1,550,685	613,363	60.4%	291,953,694,524	150,485,506,507	48.5%
4.	from Distributors	24,798,146	11,387,680	54.1%	350,052,547,710	174,404,151,077	50.2%
5.	from Dispensers	2,285,969	2,282,835	0.1%	632,110,738	631,208,631	0.1%
	Shipments to Manufacturers						
6.	from Manufacturers	151,021	77,435	48.7%	97,475,133,509	55,012,866,965	43.6%
7.	from Distributors	226,226	126,711	44.0%	12,083,288,652	5,545,996,153	54.1%
8.	from Dispensers	40,899	40,174	1.8%	1,875,916,549	1,868,059,604	0.4%
	Total	**454,800,531**	**439,623,993**	**3.3%**	**890,049,478,603**	**523,772,850,836**	**41.2%**

Source: McCann Initial Report, Table 4 and Table 5.
Note: Total row may differ from tables in McCann Initial Report due to rounding.

198. In the McCann Initial Report, Dr. McCann validates the ARCOS data against transaction data provided by Distributor Defendants and publicly available from the ARCOS Retail Drug Summary Reports. While Dr. McCann states that the corrected ARCOS data he uses are "reliable" in that they closely match the ARCOS Retail Drug Summary Reports,[274] the disproportionate removal of large shipments would introduce biases in his analysis. For example, the removal of transactions representing large shipments would result in lower 12-month average thresholds and thereby would, in general, increase the number of flagged transactions in his threshold filters which rely on these averages. Furthermore, despite significant, unresolved differences in opioid shipments between AmerisourceBergen's own transaction data and ARCOS, Dr. McCann concludes that the ARCOS dataset is reliable.[275]

199. In his Supplemental Report, Dr. McCann explains how he attributes distributor-to-dispenser transactions back to Marketing Defendants. He first uses ARCOS transaction data to follow shipments from distributors back to their originating Marketing Defendant, utilizing the Buyer and Seller DEA identification numbers.[276] In some cases, a medication is repacked and relabeled by a separate entity. Dr. McCann uses FDA drug labeler names ("Labeler Data") to identify and associate labelers with Marketing Defendants.[277] As Dr. McCann notes in this Supplemental Report, there are cases where the labeler and the manufacturer are different, but both are Marketing Defendants.[278] In these cases, Dr.

[274] McCann Initial Report, ¶ 14.

[275] McCann Initial Report, ¶¶ 15-17. AmerisourceBergen is the 2nd largest distributor of opioids in Bellwether Counties, in terms of number of transactions. See McCann Initial Report, Table 14.

[276] McCann Supplemental Report, ¶¶ 15-17.

[277] McCann Supplemental Report, ¶¶ 21-25.

[278] McCann Supplemental Report, ¶ 25.

McCann attributes a downstream transaction with a dispenser to *both the labeler and the manufacturer*.

9.2. Summary of Dr. McCann's approaches to identifying "flagged" transactions

200. In his Initial Report, Dr. McCann applies five threshold filters to the transactions from distributors to dispensers to identify suspicious transactions.[279] In his Supplemental Report, Dr. McCann applies these same five filters to transactions to dispensers that he has attributed to Marketing Defendants.[280]

201. For each of the 12 controlled substance drug codes, Dr. McCann's filters evaluate whether the total dosage units transacted between a distributor and a dispenser in a particular month exceed some threshold amount.[281] Once a distributor-to-dispenser transaction is flagged, Dr. McCann imposes the restriction that all subsequent transactions between that distributor and dispenser are also flagged, because "the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction."[282]

202. The five filters that Dr. McCann constructs in his Initial Report are:

- **Maximum monthly, trailing six-month threshold** – Flag transactions if the total dosage units shipped from the distributor to the dispenser in a month is greater than the maximum monthly dosage units over the prior six months.[283]
- **Twice trailing 12-month average threshold** – Flag transactions if the total dosage units shipped from the distributor to the dispenser in a month is greater than twice the average monthly dosage units shipped from the distributor to all retail and chain pharmacies in the entire country, over the prior twelve months.[284]
- **Three times trailing 12-month average threshold –** Flag transactions if the total dosage units shipped from the distributor to the dispenser in a month is greater than three times the average monthly dosage units shipped from the distributor to all retail and chain pharmacies in the entire country, over the prior twelve months.[285]

[279] McCann Initial Report, ¶¶ 130-151.
[280] McCann Supplemental Report, ¶¶ 26-47.
[281] Dr. McCann excludes two treatment drugs, buprenorphine and methadone, from his analysis. McCann Initial Report, FN 54.
[282] McCann Initial Report, ¶ 132.
[283] McCann Initial Report, ¶ 131.
[284] McCann Initial Report, ¶ 136.
[285] McCann Initial Report, ¶ 140.

- **Maximum 8,000 dosage units monthly** – Flag transactions if the total dosage units shipped from the distributor to the dispenser in a month exceeds 8,000 units.[286]
- **Maximum daily dosage units –** Flag transactions if the total dosage units shipped from the distributor to the dispenser in a month exceeds "a number of dosage units that varies by drug type and within some drug types by formulation."[287]

203. In Section IV of his Supplemental Report, Dr. McCann flags transactions that he attributes to Marketing Defendants simply based on whether or not the distributer-to-dispenser transactions were flagged in his Initial Report.[288] In Section V of his Supplemental Report, Dr. McCann re-applies the five threshold filters to each distributor-to-dispenser transaction that he has attributed to each Marketing Defendant.[289] Both methods are ad-hoc and fundamentally flawed and, as discussed in Section 9.3.5 below, lead to substantially different estimates of the number of suspicious transactions.

9.3. Critiques of Dr. McCann's analysis

204. All five of Dr. McCann's proposed threshold filters are ad-hoc and uninformative. The filters fail to reflect any of the underlying variance in month-to-month dosage units that may be required by pharmacies. The filters also ignore long-run trends that may have contributed to increased prescription of opioid medication in the Bellwether Counties that are unrelated to suspicious orders. Furthermore, Dr. McCann's proposed threshold filters fail to reflect any concept of variance or statistical significance. Finally, the assumption that once a transaction is flagged, all subsequent transactions should be flagged, substantially increases the number of suspicious transactions by flagging transactions that would otherwise be below his threshold and would not be flagged.[290]

9.3.1. Dr. McCann's proposed thresholds are ad-hoc and uninformative

205. Each of Dr. McCann's proposed thresholds are without basis or justification and are uninformative with regard to whether or not a transaction by a Marketing Defendant is suspicious. Dr. McCann provides no explanation or justification for why he considers his choice of thresholds to be appropriate.

[286] McCann Initial Report, ¶ 144.
[287] McCann Initial Report, ¶ 148.
[288] McCann Supplemental Report, ¶ 48.
[289] McCann Supplemental Report, ¶ 49.
[290] McCann Initial Report, ¶ 132.

206. The first threshold, "maximum monthly, trailing six-month threshold", explicitly assumes that the monthly dosage units transacted between a distributor and pharmacy can never surpass the maximum monthly dosage units in the prior six months without being deemed suspicious. Combined with the assumption that once a transaction is flagged, all subsequent transactions are also flagged, this threshold filter results in the condition that dosage units can never surpass the maximum dosage units in the *first* six months of transactions. In particular:

- Dr. McCann's data set of transactions attributable to Marketing Defendants commences on 1/1/2006. His filter would flag the first transaction that was greater than the maximum monthly transaction of the **first six months of 2006**.
- If transactions in month seven (i.e., July 2006) were less than the maximum monthly transaction in the first six months of 2006, Dr. McCann's maximum threshold declines and is more likely therefore to flag a subsequent transaction. Even years after the initial six months, any increase in monthly dosage units would be deemed suspicious.

207. Likewise, the second and third threshold filters that Dr. McCann proposes, "twice trailing 12-month average threshold" and "three times trailing 12-month average threshold," assume that any transaction two- or three-times greater than the average of a distributor's transactions with *all pharmacies* over the prior year should be deemed suspicious. In particular, the 12-month average threshold is the average of the distributor's transactions with pharmacies in all 50 states, and not just those pharmacies located in Bellwether Counties. As discussed in Section 9.3.4 below, there are a variety of factors that cause heterogeneity in the number of dosage units different pharmacies require — none of which Dr. McCann considered.

208. Dr. McCann's last two threshold filters are also completely without basis or justification. The first, "maximum 8,000 dosage units monthly," assumes a completely ad-hoc monthly limit of 8,000 dosage units. This limit is applied uniformly across pharmacies, regardless of location, customer base, or a number of other factors that affect monthly demand. The limit is also applied uniformly across time, so that the dosage units deemed suspicious in the first month of Dr. McCann's analysis is exactly the same as the last month, which is nearly a decade later. Likewise, the fifth filter "maximum daily dosage units" varies by drug type and within some drug types by formulation. For example the daily dosage limit for morphine is 500 dosage units, whereas the daily dosage limit for codeine is 1,300 units.[291] Dr. McCann does not explain how he arrives at these daily dosage units.

[291] McCann Supplemental Production. Codeine is included in Dr. McCann's analysis, but is not one of the opioids at issue in this litigation.

209. Not only are Dr. McCann's threshold filters arbitrary and unsupported, his conclusions based on these ad-hoc filters fail to incorporate any concept of statistical significance. Most events, including the amount of opioid medication required by a particular pharmacy in a particular month, involve some degree of randomness. The process of testing a hypothesis about some random event is well understood in the field of statistics.[292] For example, Dr. McCann's analysis simply asks whether the dosage units shipped to any particular pharmacy on any particular month (or in his fifth filter, by day) is greater than expected, based on previous observations or predetermined cut-offs. However, Dr. McCann's analysis follows none of the statistical procedures for determining the validity of his conclusions. His filters merely flag the data if it reaches certain thresholds, for which for he provides no basis or justification, and fail to recognize any underlying variance in the data.

210. Finally, as explained in Section 9.3.4 below, there are a number of factors that can cause month-to-month variation in dosage units required by a pharmacy. By failing to account for these underlying factors, Dr. McCann mistakenly attributes changes in the dosage units required by pharmacies to suspicious behavior.

9.3.2. Dr. McCann's assumption that all subsequent transactions should be deemed suspicious inappropriately inflates his estimate of suspicious transactions

211. Dr. McCann's assumption that once a transaction is flagged, all subsequent transactions are flagged, substantially increases the number of suspicious transactions. Dr. McCann states that he has been instructed by Counsel to assume that the distributor did not effectively investigate the first flagged transaction[293] and to flag all subsequent transactions from that distributor to that pharmacy for this drug code on the basis that, since "the Distributor did not effectively investigate the flagged transactions", then all subsequent transactions should also be flagged "because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction."[294]

212. This assumption dramatically and inappropriately inflates the estimates of suspicious orders. For example, according to Dr. McCann's maximum 8,000 dosage units monthly threshold, if the monthly transaction between a distributor and a dispenser for a given drug code exceeds 8,000 in January 2006, then all subsequent transaction for this drug code after January 2006 between the distributor and the dispenser will be automatically flagged, regardless of the actual transaction numbers in the following months and years. Under Dr.

[292] Casella, George and Roger L. Berger. Statistical Inference. Second Edition. 2002 Thomson Learning. Chapter 8.

[293] McCann Initial Report, ¶ 132.

[294] McCann Initial Report, ¶¶ 131-132. In his Supplemental Report, Dr. McCann makes the same assumption regarding flagged transactions to dispensers that he has attributed to Marketing Defendants. See ¶ 51.

McCann's assumption, even if all subsequent transactions were less than 8,000 dosage units monthly, they would still be flagged as suspicious.

213. To illustrate the effects of this assumption, I drop the assumption that once a transaction is flagged, all subsequent transactions are flagged and recalculate the shares of flagged transactions in Section V of his Supplemental Report. As Exhibit 27 and Exhibit 28 show, Dr. McCann's assumption substantially inflates the shares of flagged transactions for all five thresholds. Thus, Dr. McCann's defined thresholds and the number of flagged transactions are uninformative with regard to whether or not a transaction is suspicious.

EXHIBIT 27
Number of flagged transactions in Cuyahoga County, with and without Dr. McCann's assumption, 2006–2014

	As displayed in McCann's section V	Section V dropping Dr. McCann's assumption	Difference
1. Max 6-month	72.2%	4.0%	68.3%
2. Twice Average 12-month	9.0%	3.1%	5.9%
3. Three Times Average 12-month	5.7%	1.6%	4.1%
4. Max 8,000 Dosage Units	31.6%	7.7%	23.9%
5. Max Daily Dosage Units	73.4%	28.6%	44.8%

Source: McCann Supplemental Production.

EXHIBIT 28
Number of flagged transactions in Summit County, with and without Dr. McCann's assumption, 2006–2014

	As displayed in McCann's section V	Section V dropping Dr. McCann's assumption	Difference
1. Max 6-month	74.0%	3.9%	70.1%
2. Twice Average 12-month	11.1%	4.3%	6.8%
3. Three Times Average 12-month	7.8%	2.6%	5.3%
4. Max 8,000 Dosage Units	41.4%	13.1%	28.2%
5. Max Daily Dosage Units	79.0%	30.5%	48.6%

Source: McCann Supplemental Production.

9.3.3. Dr. McCann's methodology of attributing transactions back to Marketing Defendants results in double counting

214. In addition to inflating the number of flagged transactions by assuming that all subsequent transaction are flagged, Dr. McCann's methodology for attributing distributor-to-dispenser transactions back to Marketing Defendants in his Supplemental Report also substantially inflates the number of flagged transactions. Furthermore, as I discuss in Section 9.4, Dr. McCann's methodology tells us nothing with regard to whether or not Marketing Defendants are able to identify a transaction as suspicious.

215. In his Supplemental Report, Dr. McCann attributes a flagged transaction to Marketing Defendants if they were "either the Labeler, the Manufacturer or had included the NDC in its chargeback data" from 2006 to 2014.[295] One transaction therefore can be matched to multiple Marketing Defendants based on his proposed approach, leading to double-counting or multiple attributions of suspicious transactions. Taking the drug NDC 228287811 as an example, all flagged transactions related to this NDC are attributed to Actavis as the labeler and Allergan as the manufacturer in the chargeback data, leading to double-counting all transactions with dispensers associated with this NDC.

216. As illustrated in Exhibit 29 and Exhibit 30 below, when I correct for the double- or multiple-counting, the total numbers of flagged transactions in Section IV of Dr. McCann's Supplemental Report substantially decreases.

EXHIBIT 29
Number of flagged transactions in Cuyahoga County, with and without double-counting, 2006–2014

	As Displayed in McCann's Section IV	Correcting Double-Counting in Section IV	Difference
1. Max 6-month	1,285,621	713,224	44.5%
2. Twice Average 12-month	692,714	395,196	42.9%
3. Three Times Average 12-month	362,876	211,651	41.7%
4. Max 8,000 Dosage Units	789,159	421,684	46.6%
5. Max Daily Dosage Units	1,263,109	693,632	45.1%

Source: McCann Supplemental Production.

[295] McCann Supplemental Report, ¶ 27.

EXHIBIT 30
Number of flagged transactions in Summit County, with and without double-counting, 2006–2014

	As Displayed in McCann's Section IV	Correcting Double-Counting in Section IV	Difference
1. Max 6-month	817,441	451,336	44.8%
2. Twice Average 12-month	640,097	354,806	44.6%
3. Three Times Average 12-month	404,046	227,812	43.6%
4. Max 8,000 Dosage Units	627,317	336,131	46.4%
5. Max Daily Dosage Units	814,604	448,810	44.9%

Source: McCann Supplemental Production.

217. The attribution of a single distributor-to-dispenser transaction being attributed to two or more Marketing Defendants also inflates the number of flagged transactions in Section V of Dr. McCann's Supplemental Report. This includes transactions for which two different Marketing Defendants serve as the manufacturer and labeler. There are also a number of NDCs that are linked to multiple manufacturers from the same data source. For example, NDC 228287811 is linked to Allergan, Qualitest, and Teva as the manufacturer from the chargeback data. Because Dr. McCann recalculates his threshold filters for each Marketing Defendant in Section V, it is impossible to simply remove duplicate transactions from his analysis without first assigning a transaction to a single Marketing Defendant. This duplication of transactions inflates Dr. McCann's number of flagged transactions in Section V of his Supplemental Report.

9.3.4. Dr. McCann's analysis ignores factors that could easily affect month-to-month variation and long-term growth in opioid shipments

218. The volume of prescription medication that any pharmacy requires is not constant from month-to-month or over the long-run. There are a number of factors that affect a pharmacy's required shipments in the short- and long-run, all of which Dr. McCann's threshold filter analysis completely ignores. Consideration of these factors indicate that month-to-month fluctuations in shipments do not necessarily indicate suspicious behavior. Likewise, there are a number of factors that indicate that opioid usage would naturally increase in Bellwether Counties over the period Dr. McCann considers. I discuss some of these factors in the remainder of this subsection.

219. Distributors and pharmacies hold an inventory of medications, which they distribute to customers.[296] This inventory is depleted as the distributor ships drugs to pharmacies and as

[296] "Managing inventory: What retail can learn from pharma," Gary Wollenhaupt, October 15, 2018.

pharmacies fill prescriptions and stock expires. Distributors order replacement stock from manufacturers and pharmacies order replacement stock from distributors to replenish their inventories. However, the depletion and replenishment of inventory is not always constant or predictable. Therefore, in some months the transacted dosage units might be especially low, and some months the transacted dosage units might be especially high. Any minor deviation from the threshold amount that Dr. McCann imposes would define fluctuations due to inventory management as suspicious.

220. When considering what medication to prescribe to a patient, physicians must consider a number of factors, including efficacy, affordability, individual patient characteristics, and safety. Over time, these factors can and do change, leading physicians to reassess and possibly change prescribing decisions. The introduction of a low-cost generic or changes in insurance policy can change the cost to patients.[297] In addition to their own professional experience and education, doctors also rely on medical journals to keep them up-to-date on new clinical trials and medical research.[298] Even physician-specific characteristics influence prescribing behavior.[299] These factors, in turn, affect the volume of shipments that the pharmacy requires. If some innovation or change in price makes a certain opioid medicine suddenly more attractive to physicians and patients, distributors will see an increase in demand for that product. This does not necessarily indicate that the transactions are suspicious; only that the nature of demand changed.

221. Economic and social factors could also contribute to the increase in opioid use. For example, a study showed that the use of opioids can be "a refuge from physical and psychological trauma, concentrated disadvantage, isolation, and hopelessness."[300] The same study goes on to say that the "2008 financial crisis along with austerity measures…have further eroded physical and mental well-being."[301] While this study does not distinguish between legitimate and illegal opioid use, this "erosion" in the wake of the financial crisis could help explain the trend that we see in the data: while opioid shipments increased from 2006-2011, there is a decline in shipments over the 2012-2014 period.

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[297] Thomas S. Rector et al., "Effect of Tiered Prescription Copayments on the Use of Preferred Brand Medications," Medical Care, 41(3), 2003, pp. 398–406. Douglas E. Mager and Emily R. Cox, "Relationship Between Generic and Preferred-Brand Prescription Copayment Differentials and Generic Fill Rate," The American Journal of Managed Care, 13(6), 2007, pp. 347–352 at pp. 350–351. Marcus Dillender, "What Happens When the Insurer Can Say No? Assessing Prior Authorization as a Tool to Prevent High-Risk Prescriptions and to Lower Costs," Journal of Public Economics, 165(1), 2018, pp. 170–200 at p. 171.

[298] World Health Organization Report, "Guide to Good Prescribing: A Practical Manual," Document WHO/DAP/94.11, 1994 ("WHO Report (1994)"), pp. 86–93.

[299] Chintagunta et al. (2009); Chan et al. (2013); Kalra et al. (2011).

[300] "Opioid Crisis: No Easy Fix to Its Social and Economic Determinants," Dasgupta, Beletsky, and Ciccarone, Am J Public Health, February, 2018, 108(2): 182–186.

[301] "Opioid Crisis: No Easy Fix to Its Social and Economic Determinants," Dasgupta, Beletsky, and Ciccarone, Am J Public Health, February, 2018, 108(2): 182–186.

222. A large share of opioid prescriptions in the U.S. are paid for by third party payers ("TPPs") such as Medicare, Medicaid, and private insurance; and this share is increasing over time.[302] In 1999, Medicaid and Medicare only covered 9% of opioid costs, while 53% of opioid costs were borne out-of-pocket.[303] By 2012, 35% of opioid costs were covered by either Medicaid or Medicare, while only 18% of opioid costs were out-of-pocket payments.[304] By shifting the cost of opioid medications off of customers, TPPs are influencing opioid prescriptions and the long-term trends in opioid usage.

223. Finally, demographic changes in Bellwether Counties are likely to have contributed to the increase in prescribed opioids. Although the population decreased in both counties from 2006 to 2014, the number of individuals age 65 and over increased by 1.8% between 2006 and 2014 in Cuyahoga County and by 10.1% in Summit County. In fact, several data sources have shown that "older adults use opioids at high rates and over the long-term".[305] This upward trend in residents age 65 and older would indicate that the total number of opioid medications prescribed in Bellwether Counties would naturally rise during the years in Dr. McCann's analysis. In fact, Dr. Rosenthal's regression acknowledges that demographic and economic variables can explain some of the increase in shipments over time, which would trigger more suspicious orders.[306]

[302] Zhou, Chao, et al., 2018, "Payments for Opioids Shifted Substantially to Public and Private Insurers While Consumer Spending Declined, 1999–2012," *Health Affairs* 35(5).

[303] Zhou, Chao, et al., 2018, "Payments for Opioids Shifted Substantially to Public and Private Insurers While Consumer Spending Declined, 1999–2012," *Health Affairs* 35(5).

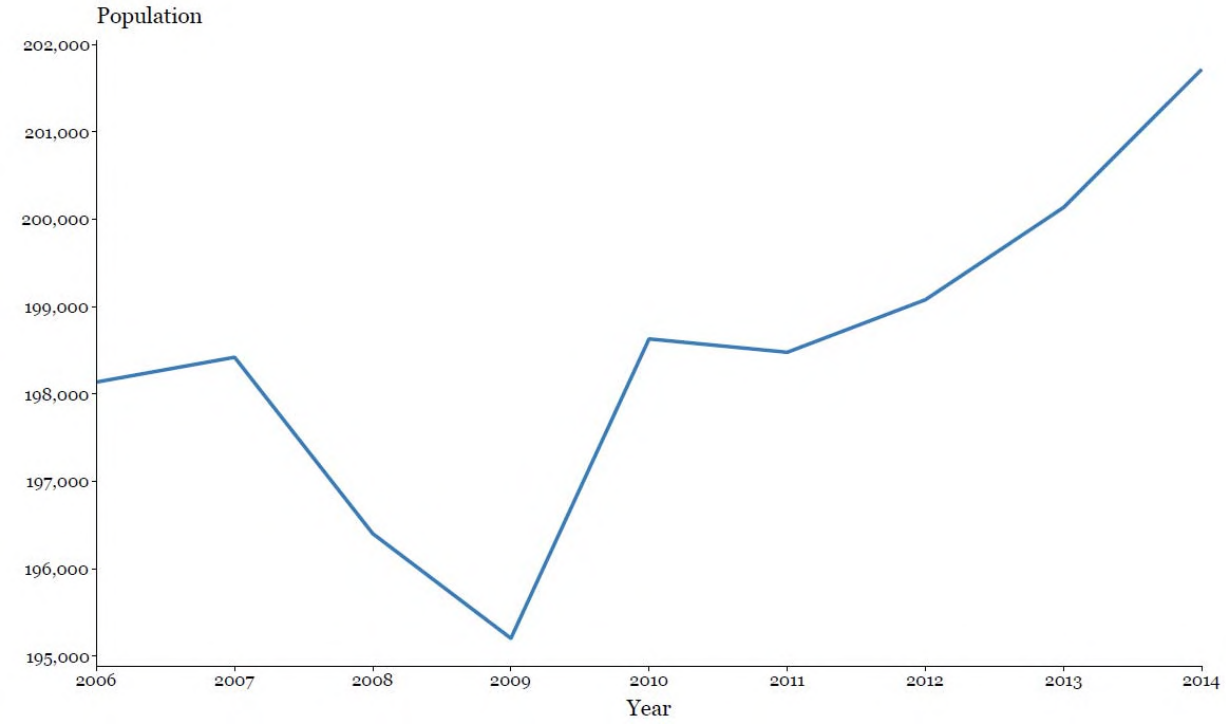
[304] Zhou, Chao, et al., 2018, "Payments for Opioids Shifted Substantially to Public and Private Insurers While Consumer Spending Declined, 1999–2012," *Health Affairs* 35(5).

[305] "The Opioid Public Health Emergency and Older Adults", Tilly, Skowronski, and Ruiz, December, 2017, p. 4.

[306] Rosenthal Report, Sections VIII and IX.

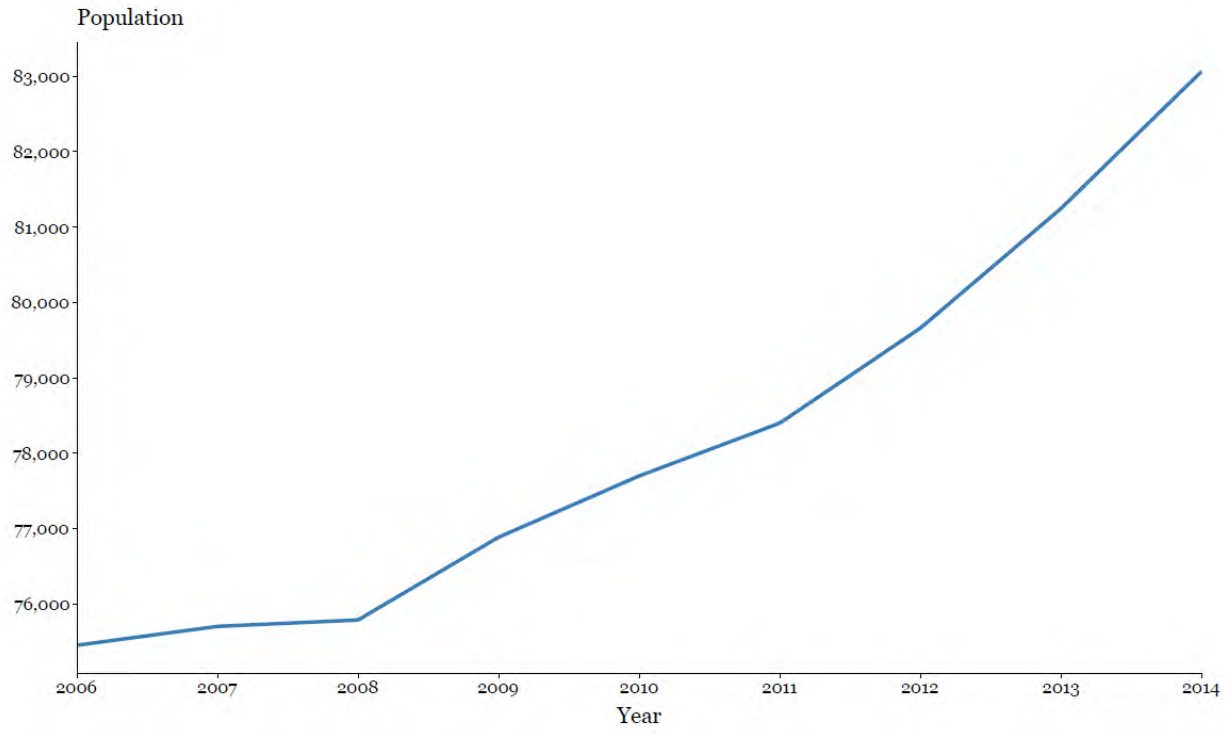
EXHIBIT 31

Number of residents 65 and over in Cuyahoga County, 2006–2014



Source: US Census.

EXHIBIT 32
Number of residents 65 and over in Summit County, 2006–2014



Source: US Census.

224. The list above is not an exhaustive account of the factors that can affect month-to-month variation in transactions, or the long-run trend in transactions. Dr. McCann has accounted for none of them in his analysis. Without accounting for such factors, his analysis and therefore his conclusions are unreliable and uninformative.

9.3.5. Dr. McCann's various methodologies result in substantially different estimates of suspicious transactions

225. Finally, Dr. McCann's various methodologies result in substantially different estimates in the number of transactions that should have been flagged as suspicious. The inability of Dr. McCann's analysis to result in a consistent estimate of suspicious transactions further suggests that his analysis is ad-hoc, depending on the choice of threshold, and is unreliable as an indicator of suspicious transactions.

226. Differences in the number of flagged transactions also arise due to the methodology he adopts to flag transactions. In Section V of his Supplemental Report, Dr. McCann applies his threshold filters to the 2006–2014 transactions with dispensers that he has attributed to Marketing Defendants. Whereas in Section IV of his Supplemental Report, he flags

transactions with dispensers that he attributed back to Marketing Defendants according to whether or not they were flagged in his Initial Report.[307]

227. For example, Exhibit 33 reports Dr. McCann's estimates of flagged transactions in Cuyahoga County, using his five different threshold filters and his two different methods for attributing transactions to Marketing Defendants. In Section IV of his Supplemental Report Dr. McCann's proposed threshold filters yield estimates of flagged transactions in Cuyahoga County that vary from 26.0% to 83.3%, depending on which threshold filter he applies. Similarly, in Section V, Dr. McCann's results indicate that the share of flagged transactions is between 5.7% and 73.4%.

228. In addition to the choice of threshold, differences in the number of flagged transactions also arise due to the methodology he adopts to flag transactions. In Section V of his Supplemental Expert Report, Dr. McCann applies his threshold filters to the 2006–2014 transactions with dispensers that he has attributed to Marketing Defendants. Whereas in Section IV of his Supplemental Expert Report, he categorized transactions with dispensers that he attributed back to Marketing Defendants according to whether they were flagged or not in his Initial Report.[308] For example, for the three-times average 12-month threshold, Exhibit 33 reports 26% of transactions are flagged in Section IV, whereas only 5.7% of transactions are flagged in Section V.

EXHIBIT 33
Dr. McCann's own methodologies produce inconsistent estimates of flagged transaction In Cuyahoga County, 2006–2014

Method	Section IV	Section V
1. Max 6-month	76.0%	72.2%
2. Twice Average 12-month	45.6%	9.0%
3. Three Times Average 12-month	26.0%	5.7%
4. Max 8,000 Dosage Units	42.6%	31.6%
5. Max Daily Dosage Units	83.3%	73.4%

Source: McCann Supplemental Report.

229. Dr. McCann's different methodologies produce similarly inconsistent results in Summit County. For the different thresholds Dr. McCann uses, Exhibit 34 reports that Dr. McCann's estimates of flagged transactions in Summit County, using his Section IV methodology, vary from 40.5% to 86.6%. In Section V, he estimates that between 7.8% and 79.0% of

[307] McCann Supplemental Expert Report, ¶¶ 48-49.
[308] McCann Supplemental Expert Report, ¶¶ 48-49.

transactions are flagged. Dr. McCann's estimates for the same threshold also differ between Section IV and Section V. For example, for the three-times average 12-month threshold, Exhibit 34 reports 40.5% of transactions are flagged in Section IV, whereas only 7.8% of transactions are flagged in Section V.

EXHIBIT 34
Dr. McCann's own methodologies produce inconsistent estimates of flagged transaction In Summit County, 2006–2014

Method	Section IV	Section V
1. Max 6-month	75.4%	74.0%
2. Twice Average 12-month	62.9%	11.1%
3. Three Times Average 12-month	40.5%	7.8%
4. Max 8,000 Dosage Units	52.4%	41.4%
5. Max Daily Dosage Units	86.8%	79.0%

Source: McCann Supplemental Report.

9.4. Dr. McCann's analysis does not accurately reflect the information available to Marketing Defendants

230. Dr. McCann's analysis does not reflect the information that was available to Marketing Defendants. His analysis relies on detailed, transaction-level, ARCOS data. However, "[n]o one within the supply chain ha[d] access to ARCOS."[309] Instead, Dr. McCann claims that Marketing Defendants could have used two different data sources, chargeback data and IQVIA/IMS data, to identify suspicious transactions.[310] Notably, Dr. McCann does not perform any analysis using these datasets, and does not evaluate whether the data were available to Marketing Defendants at the time orders were placed, but only asserts that these datasets are sufficient to monitor transactions for suspicious orders.

231. In particular, Dr. McCann states:

- "Assuming the limited chargeback data provided to me is typical in nature and scope of that available to Manufacturers, the Manufacturer Defendants could have monitored orders from Dispensers, primarily retail and chain pharmacies, if they

[309] See "Questions for the Record from Senator Charles E. Grassley To President and CEO of Healthcare Distribution Alliance, U.S. Senate Committee on the Judiciary – Oversight on the Ensuring Patient Access and Drug Enforcement Act," answered on January 3, 2018. It is also my understanding that ARCOS data only recently became available to Teva in February 2019 (Telephone call on May 10, 2019 with Joseph Tomkiewicz, Manager DEA Compliance at Teva).

[310] McCann Supplemental Report, ¶¶ 18-20.

received chargeback data for all sales of all opioids they shipped to other Manufacturers and to Distributors [emphasis added]."[311]

- "Assuming the IQVIA/IMS Data provided to me is typical in nature and scope to that which was available to Manufacturers, a Manufacturer Defendant could have known where some or all of its drugs were being prescribed [emphasis added]."[312]

232. Contrary to Dr. McCann's claim, neither chargeback data that is available to Marketing Defendants nor IQVIA/IMS data would be sufficient to perform the analysis presented in his Supplemental Report, which is based on ARCOS data.

233. The supply chain of pharmaceutical products in the United States involves three tiers from upstream to downstream suppliers: pharmaceutical manufacturers, wholesale distributors, and dispensers (e.g., pharmacies and hospitals).

234. Pharmaceutical manufacturers produce and manage drug distribution from the manufacturing facilities to wholesale distributors. Wholesale distributors purchase pharmaceutical products from manufacturers and distribute them to pharmacies across the country. As an intermediary, wholesale distributors provide warehouse services and inventory management and save costs by efficiently consolidating orders from a variety of pharmacies. Wholesale distributors are the largest purchasers from manufacturers and manage over 91% of pharmaceutical sales revenue.[313] Furthermore, the U.S. pharmaceutical distribution industry is highly concentrated with three companies: AmerisourceBergen, Cardinal Health, and McKesson, collectively comprising over 85% of all revenues from the drug distribution.[314]

235. Pharmacies are at the next downstream level of the supply chain. Pharmacies purchase drugs from wholesale distributors and dispense prescription drugs to patients. There are several types of pharmacies, including chain pharmacies and mass merchants with pharmacies, independent pharmacies, and mail-order pharmacies.[315] In some circumstances, large chain pharmacies can choose to purchase generic drugs directly from

[311] McCann Supplemental Report, ¶ 19.

[312] McCann Supplemental Report, ¶ 20.

[313] "Financing and Distribution of Pharmaceuticals in the United States," JAMA, 2017, 318(1): pp. 21-22. "Modern Distribution Management (MDM). 2016 MDM market leaders: top pharmaceuticals distributors." https://www.mdm.com/2016-top-pharmaceuticals-distributors. 2017. Accessed May, 6, 2019.

[314] "Financing and Distribution of Pharmaceuticals in the United States," JAMA, 2017, 318(1): pp. 21-22. "Modern Distribution Management (MDM). 2016 MDM market leaders: top pharmaceuticals distributors." https://www.mdm.com/2016-top-pharmaceuticals-distributors. 2017. Accessed May, 6, 2019.

[315] From a review of Dr. McCann's production, it appears that he excludes online and mail-order pharmacies from his analysis. This exclusion is not indicated in Dr. McCann's report.

manufacturers.[316] In other circumstances, large pharmacies may negotiate prices directly with manufacturers, but rely on wholesale distributors to deliver the drugs. In this case, the wholesale distributor charges the manufacturer for the difference between the price that the wholesale distributor negotiated with the manufacturer and the price that the pharmacies negotiated with the manufacturer (known as a "chargeback").[317]

236. Dr. McCann opines that Marketing Defendants could have "monitored orders from dispensers, primarily retail and chain pharmacies, if they received chargeback data for *all* sales of all opioids they shipped to other Manufacturers and to Distributors [emphasis added]."[318] However, chargebacks only occur when a Marketing Defendant and a dispenser have contracted a price that is different from the price at which the Marketing Defendant sells to the distributor. It is my understanding that 50% of controlled substances sales for Teva USA do **not** have chargeback data.[319]

237. Furthermore, chargeback contracts generally exist for a manufacturer's larger, established customers. Pharmacies that illegally or inappropriately dispense pharmaceutical products (e.g., pill mills) are unlikely to have contracts with large manufacturers and are highly unlikely to enter chargeback contracts that create documentation of their purchasing and dispensing habits. Put simply, bad actors do not want to generate chargebacks and will buy products at wholesale acquisition costs (WAC) to avoid raising red flags.[320]

238. Dr. McCann also opines that Marketing Defendants could have used IQVIA/IMS data to flag transactions.[321] However, the IQVIA/IMS data available to Marketing Defendants does not connect the prescription data between prescribers and individual pharmacies. As a result Marketing Defendants cannot use IQVIA/IMS data to determine which pharmacies prescribers are using to have prescriptions filled. I understand that Teva USA has requested this information from IQVIA, but has been told IQVIA is not permitted to provide that level of detail to manufacturers. It is also my understanding that some chain pharmacies do not provide data to IQVIA, or provide the data with some information blinded or eliminated.[322]

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[316] "Large retail chains also buy directly from generic manufacturers, pitting one generic manufacturer against others to obtain the lowest generic price." See Berndt, E. and J. Newhouse, "*Pricing and Reimbursement in US Pharmaceutical Markets*," in P. Danzon and S. Nicholson eds., *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, New York: Oxford University Press, 2012, p. 218.

[317] "The wholesaler keeps track of sales to various customers under prices negotiated between the manufacturer and the customer. The wholesaler then "charges back" the manufacturer for any difference between the negotiated prices paid by the customer and the wholesaler's cost of goods (WAC)." See "*Follow the Pill*, p. 19.

[318] McCann Supplemental Report, ¶ 19.

[319] Telephone call on May 10, 2019 with Joseph Tomkiewicz, Manager DEA Compliance at Teva.

[320] Telephone call on May 10, 2019 with Joseph Tomkiewicz, Manager DEA Compliance at Teva.

[321] McCann Supplemental Report, ¶ 20.

[322] Telephone call on May 10, 2019 with Joseph Tomkiewicz, Manager DEA Compliance at Teva.

10. PLAINTIFFS' ABATEMENT ANALYSES ARE NOT CAUSALLY LINKED TO THE DEFENDANTS' ALLEGED CONDUCT

239. Plaintiffs' experts, Dr. Liebman and Dr. Alexander ("Plaintiffs' Abatement Experts"), have submitted expert reports purporting to estimate the cost of abating the opioid abuse crisis. Dr. Liebman has presented opinions on "identifying how the Communities can best utilize the tools and practices available to implement programs aimed at furthering the communities' efforts to ameliorate and abate the crisis they face; and (ii) estimating the cost of providing these services."[323] Dr. Alexander has estimated national abatement costs for "additional evidence-based and evidence- informed measures and approaches [that] should be used in Cuyahoga and Summit Counties to reduce opioid-related morbidity and mortality."[324]

10.1. Plaintiffs' abatement experts do not isolate the abatement costs required because of the Defendants' alleged conduct

240. Plaintiffs' Abatement Experts have not performed any analysis to link their estimates of abatement costs to the Defendants' alleged conduct.

241. Dr. Liebman acknowledged in his deposition that in estimating abatement costs for the Bellwether Counties, he has not considered the marketing practices of any Defendant.[325] More broadly, Dr. Liebman has not rendered an opinion on the "role or responsibility of any defendant in causing … the opioid crisis."[326] Furthermore, Dr. Liebman also acknowledged that he had not considered if "the opioid crisis would look any different today if any one of the manufacturers had not marketed its opioid prescription opioid products."[327] Similarly, in estimating national abatement costs, Dr. Alexander did not offer any opinions on the marketing practices of Defendants or the potential impact of the alleged conduct.[328]

242. Plaintiffs' Abatement Experts' estimates of abatement costs are not causally linked to the Defendants' alleged conduct. As a result, Plaintiffs' Abatement Experts do not explain why any of the abatement costs would not have otherwise been incurred in the absence of the Defendants' alleged conduct.

[323] Liebman Report, ¶ 2.
[324] Alexander Report, ¶¶ 13, 15.
[325] Deposition of Dr. Jeffrey Liebman, May 3, 2019 ("Liebman Deposition"), pp. 65:22–66:1.
[326] Liebman Deposition, p. 55:2—5.
[327] Liebman Deposition, p. 58:13–23.
[328] Deposition of Dr. G. Caleb Alexander, April 26, 2019 ("Alexander Deposition"), pp. 294:11–295:4.

10.2. Plaintiffs' Abatement Experts do not apportion their estimates of the abatement costs

243. Plaintiffs' Abatement Experts have not performed any analyses to apportion their estimates of the abatement costs to medically unnecessary prescribing or the products associated with the Marketing Defendants.

244. Dr. Alexander presents no analyses to show what portion of his estimated abatement costs would be incurred by the Bellwether Counties. In particular, Dr. Alexander estimates national abatement costs which include federal, state and private costs.[329] In estimating these costs, Dr. Alexander acknowledged that he did not consider "what Cuyahoga or Summit County have been doing thus far or how effective those measures have been [...]"[330] Nor does he account for "how much extra have Cuyahoga and Summit County had to incur in terms of their own costs because of anything relating to the opioid epidemic [...]"[331] Dr. Alexander admitted that his model "wasn't focused on figuring out who should shoulder the costs."[332]

245. Furthermore, Plaintiffs' Abatement Experts' estimates of abatement costs do not:

a. Assess harm caused by any particular branded or generic opioid product.[333]

b. Account for harm caused by illicit opioid products.[334]

c. Distinguish between federal, state or county sources of funding.[335]

246. In summary, the Plaintiffs' Abatement Experts provide no analyses of what portion of the estimated abatement costs are:

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[329] Alexander Deposition, pp. 320:23–321:20.

[330] Alexander Deposition, pp. 308:25–309:12.

[331] Alexander Deposition, p. 322:3–9.

[332] Alexander Deposition, p. 321:18–20.

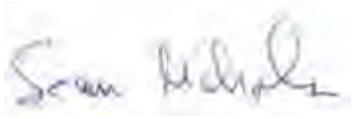
[333] Alexander Deposition, pp. 296:3–11, 298:3–11.

[334] Alexander Deposition, pp. 300:23-301:13; Liebman Deposition, p. 73:1—12.

[335] Currently, both Bellwether Counties receive funding from several federal sources, including the Justice Department and the Substance Abuse and Mental Health Services Administration. For example, Justice Department awards $1.8 million to support data sharing, drug courts and other programs in Cuyahoga and Lucas County," Department of Justice: U.S. Attorney's Office, Northern District of Ohio, October 1, 2018, available at https://www.justice.gov/usao-ndoh/pr/justice-department-awards-18-million-support-data-sharing-drug-courts-and-other, accessed on May 10, 2019; County of Summit ADM Board, "2017 Report to the Community, p. 7, available at https://www.admboard.org/Data/Sites/25/18adm04-annualrpt_8.5x11_r8_web.pdf, accessed on May 19, 2019 ; Cuyahoga ADAMHS Board, "Calendar Year 2019: ADAMHS Board – Total Budget Summary," p. 1, available at http://adamhscc.org/pdf_adamhscc/en-US/CY2019%20Operating%20Budget.pdf, accessed on May 10, 2019. See also Bipartisan Policy Center, "Tracking Federal Funding to Combat the Opioid Crisis," March, 2019, pp. 86-88, available at https://bipartisanpolicy.org/wp-content/uploads/2019/03/Tracking-Federal-Funding-to-Combat-the-Opioid-Crisis.pdf, accessed on May 9, 2019. See also Liebman Deposition, pp. 289:13–290:9; Liebman Deposition, p. 130:2–16; Alexander Deposition, pp. 320:23–322:9.

a. Incurred by the Bellwether Counties; or

b. Are attributable to the harm caused the Defendants' alleged conduct.



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Sean Nicholson, Ph.D.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 18-op-45090 *The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 17-op-45004	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

ERRATA SHEET FOR EXPERT REPORT OF SEAN NICHOLSON, PH.D., DATED MAY 10, 2019

June 4, 2019

1. ERRATA

- Footnote 68: Replace "¶ 7." with "¶ 6."
- ¶ 83 d: replace "For each year from 2006–2011" with "For each year from 2011–2016"
- Footnote 154: Amend "McGuire Damages Report, ¶ 11 and ¶¶ 133–134." to "McGuire Damages Report, ¶ 11; McGuire Public Nuisance Report ¶¶ 133–134."
- Footnote 193: Replace "pp. 3-5" with "pp. 2-5"
- ¶ 145: Replace "paper published in 1999" with "paper published in 1997"
- Footnote 211: Replace "p. 232." with "p. 218."
- Footnote 316: Replace "p. 218." with "p. 8."
- Footnote 326: Replace "55:2—5" with "63:11—14"
- Footnote 327: Replace "58:13—23" with "66:22—67:8"
- Footnote 334: Replace "73:1—12" with "81:20—82:6"
- Footnote 335: Replace "289:13—290:9" with "303:21—304:15"
- Footnote 335: Replace "130:2—16" with "139:21—140:10"